



Strong recruitment for EMD-RX5 Phase 3 trial

HIGHLIGHTS

Phase 3 trial on track to conclude July 2023; To date:

- **50** patients currently dosed;
- **83 additional** patients waiting for final eligibility assessment ahead of dosing
- **1,830 patients registered** for pre-screening, demonstrating strong patient demand

Recruitment and dosing expected to accelerate supported by Emyria's Emerald Clinics and final two sites (of a total of 9), and based in **ACT** and **SA**, to commence dosing this week

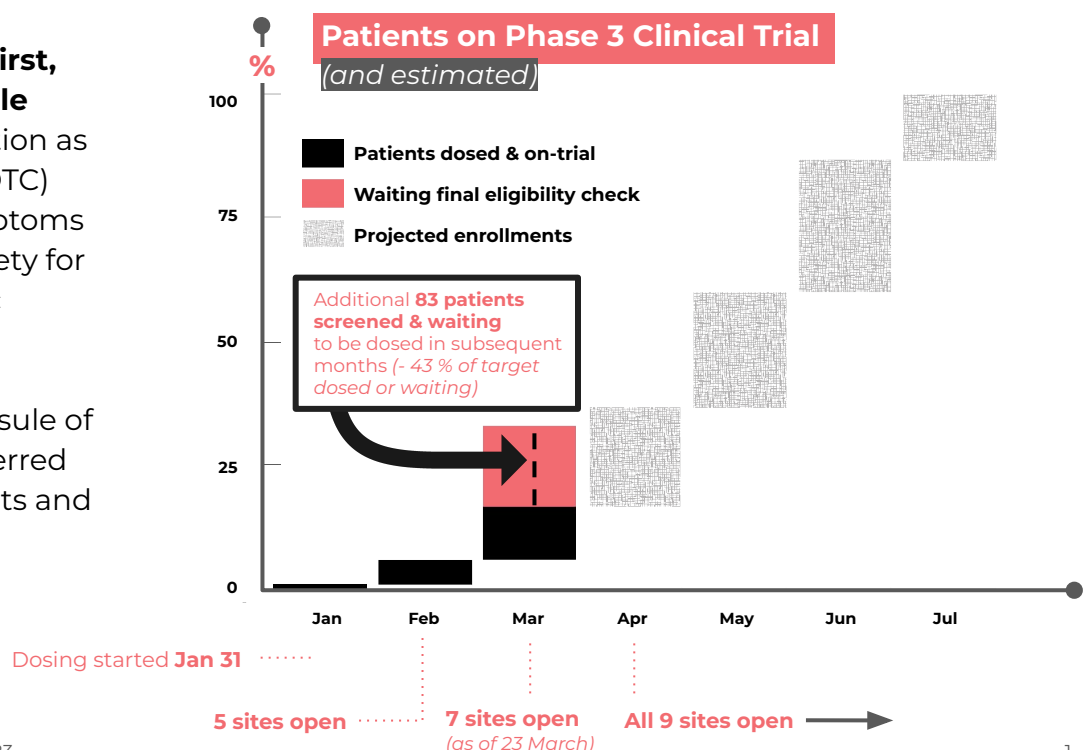
EMD-RX5 has a Large Potential Patient Market: Mild anxiety and stress affect up to 15% of the adult population ¹, with a higher prevalence in patients with chronic disease, such as chronic pain, which affects around 2.8 million adults in Australia ²; No OTC treatment currently available for Emyria's initial target indication; EMD-RX5 has the potential to address a significant unmet need in the OTC market as well as expand to other markets and indications

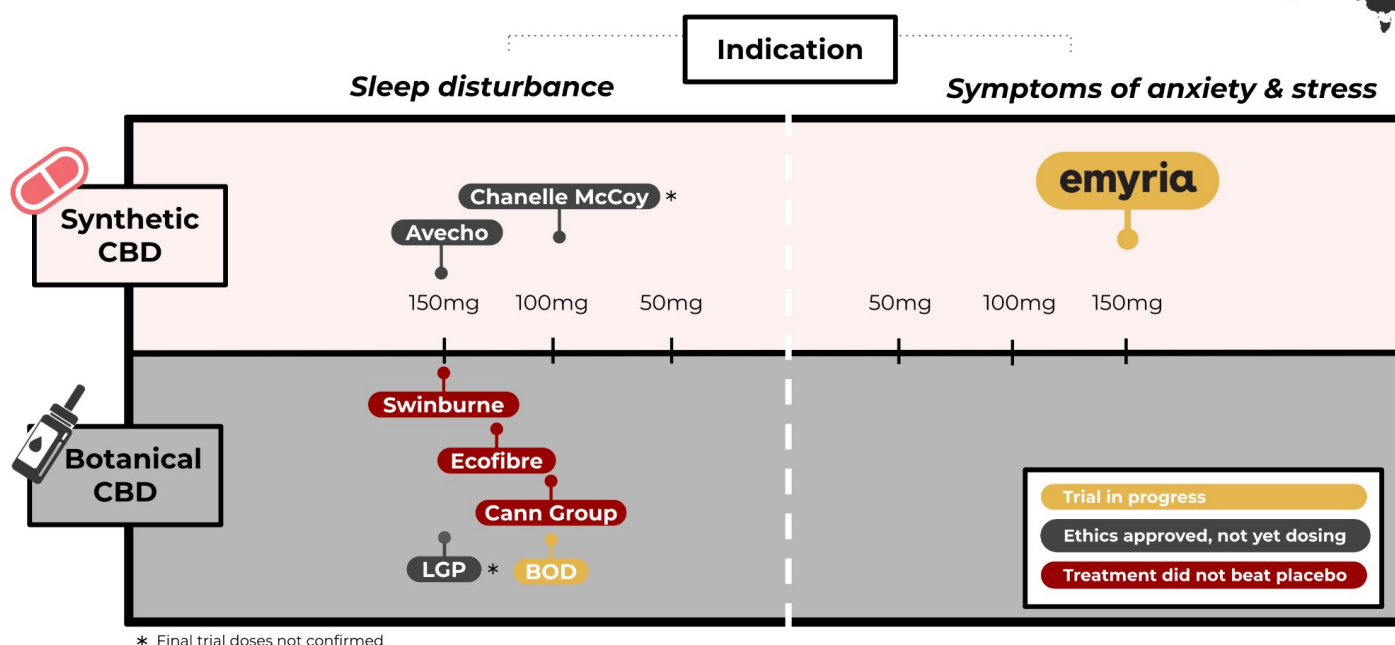
Emyria Limited (ASX: EMD), (Emyria or the Company) a clinical stage biotech, is pleased to share that 50 patients have been successfully enrolled and over 100 patients successfully screened in a pivotal Phase 3 clinical trial to support the registration of EMD-RX5 as an over-the-counter medicine.

Emyria's OTC trial program is on track to complete recruitment by July 2023 with a clinical efficacy read-out anticipated in the subsequent month.

EMD-RX5 is Emyria's first, Ultra-Pure CBD capsule targeting TGA registration as an over-the-counter (OTC) treatment for the symptoms of mild stress and anxiety for patients with a chronic health condition.

EMD-RX5 is a solid capsule of Ultra-Pure CBD, a preferred dosage form for patients and prescribers.





Towards an OTC medication

Currently, the market for registered CBD medicine is dominated by Jazz Pharmaceuticals' Epidyolex oil, a prescription medication for rare seizure disorders that generates over AUD\$1B in annual sales globally.³

While the TGA has allowed low dose CBD (<150mg/day) to be registered as an OTC medicine since December 2020, no CBD product has yet achieved this registration.⁴

Emyria's EMD-RX5 is a proprietary formulation of Ultra-Pure CBD and has been developed as a potential over-the-counter CBD medication.

EMD-RX5 development was based on insights from Emyria's unique Real-World Data gathered with over 8,000 patients prescribed pharmaceutical-grade cannabinoid medicines at their clinical service subsidiary, Emerald Clinics.

Notably, EMD-RX5 contains no THC or impurities, and requires less cost, energy, and water to produce than plant-based CBD products. In a head-to-head PK study EMD-RX5 demonstrated excellent bioavailability, safety, tolerability, and lower dose variability compared to Epidyolex oil.⁵

Emyria's initial target indication is to treat the symptoms of mild anxiety and stress in patients with a chronic condition. **Anxiety and stress affect up to 15% of the adult population** with a higher prevalence in patients with chronic disease, such as chronic pain which affects around **2.8 million adults in Australia**.^{1,2} Emyria's Real World Data suggests up to 50% of patients with Chronic Pain experience anxiety and stress symptoms. There is currently no OTC treatment for these symptoms and Emyria sees a significant opportunity for EMD-RX5 to address this unmet need in the OTC market.

EMD-RX5 is the only CBD medication targeting the symptoms of anxiety and stress and is aiming to be the first to market.

1. <https://www.aihw.gov.au/reports/burden-of-disease/abds-impact-and-causes-of-illness-and-death-in-aus/summary>
 2. AIHW "Chronic Pain In Australia" (published May 2020)
 3. <https://investor.jazzpharma.com/news-releases/news-release-details/jazz-pharmaceuticals-announces-full-year-and-fourth-quarter-2022>
 4. <https://www.tga.gov.au/news/media-releases/over-counter-access-low-dose-cannabidiol>
 5. See ASX release 25 May 2022

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KEY PHASE 3 INFORMATION:

Study design, product and participant details:

A multi-site, parallel-arm, randomised, double blind, placebo-controlled study to investigate the effect of EMD-RX5 on symptoms of psychological distress in adults with chronic pain.

300 participants aged 18-70 with symptoms of stress and a background of chronic pain will be randomised to one month of treatment with either 50mg EMD-RX5, 150mg EMD-RX5 or matching placebo.

Primary endpoint:

To determine the effect of EMD-RX5 treatment on symptoms of psychological distress in participants with chronic pain through change in self-reported DASS-21 score from baseline to Week 4.

Patient registration: <https://trials.evrima.com/stress-anxiety-medical-study>



"An accessible, convenient and effective over-the-counter treatment for psychological distress could have a significant impact on the quality of life and health outcomes for patients, especially those with chronic disease."

We are very pleased that patient recruitment for our clinical trial is strong and I look forward to updating the market as our program advances "
- Emyria's Managing Director, Dr Michael Winlo

- This release has been approved by the Board of Emyria. -

FOR FURTHER INFORMATION

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UPCOMING MILESTONES

CLINICAL PROGRAMS		PRE-CLINICAL + THERAPY PROGRAMS	
"direct-to-consumer"		New Drug Discovery	MDMA-assisted therapy
Formulation optimisation (RX5) ✓	Formulation optimisation (RX7) ✓	Continuous creation & screening ✓	Protocol developed ✓
Phase 1 study done ✓	Phase 1	First patent family filed ✓	Clinical partnerships ✓
Phase 3 commencement ✓	Pre-IND (FDA)	US-focused preclinical program ✓	Real-World Data system ✓
Regulatory submission	Pivotal trials	Metabolic studies ✓	MDMA supply secured ✓
Commercial strategy Australia		Lead selection	Therapist training
Commercial strategy Europe		Phase 1 trials	First patient
Commercial strategy USA		Global commercial strategy	Global commercial strategy

ABOUT EMYRIA | emyria.com

Emyria Limited is a clinical drug development and care delivery company focused on accelerating drug development and improving patient outcomes in neuroscience and mental health via:

- **Drug Development:** Emyria is developing multiple, proprietary, Ultra-Pure cannabinoid dose forms suitable for registration against multiple indications. Emyria's first dose form, EMD-RX5, is in Phase 3 trials.
- **New Drug Discovery:** Inspired by MDMA, Emyria is developing one of the world's largest libraries of MDMA-like compounds with partner, the University of Western Australia.
- **Proprietary Real-World Data (RWD):** Emyria gathers robust and ethically-sourced data with patients cared for at Emyria's own specialist clinical service (Emerald Clinics). Emyria RWD can help support drug development and care model improvement.

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