ASX Announcement
09 Oct 2023

emyria

A clinical stage biotech informed by patient experience.
Tackling unmet needs in neuroscience and mental health.

Emyria's Clinic Achieves Key MDMA-AT Dosing Milestone

HIGHLIGHTS

- Emyria safely completes first participant dosing for its MDMA-assisted therapy ('MDMA-AT') program since the TGA descheduling of MDMA in July 2023
- This significant milestone is believed to be an Australian first for a private specialist clinic operating distinctively from academic centres or a public/private hospital
- Milestone initiates both the active treatment phase of Emyria's MDMA-AT program and the accumulation of Real-World Data to support further innovation and payer engagement
- MDMA-AT for Post-Traumatic Stress Disorder ('PTSD') demonstrated to be highly effective and safe in second Phase 3 clinical trial published by MAPS last month [1]

Emyria Limited (ASX: EMD) ("Emyria", or the "Company") is pleased to announce the successful commencement of dosing for the first participant of its ethics-approved MDMA-assisted therapy trial, EMDMA-001. This significant milestone occurred without any safety concerns and is believed to be a first for a private specialist clinic operating distinctively from academic centres and both public and private hospitals.

The EMDMA-001 trial serves as the foundation for Emyria's Authorised Prescriber ('AP') offering for MDMA-AT by equipping Emyria's clinical staff with an ethics-approved protocol and preparing the team for the AP program's stringent requirements. The trial also puts Emyria in a leadership position as very few specialists currently meet the necessary criteria for AP status. As Emyria's trial is now in active treatment, it further bolsters the Company's readiness, strengthens its AP application process and starts to generate robust clinical evidence to support payer engagement as well as Emyria's drug development programs. A successfully initiated AP program for MDMA-AT broadens patient access to Emyria's innovative services.

Drawing on its experience providing care with recently rescheduled treatments and capturing Real-World Data with over 10,000 patients to date at Emerald Clinics, Emyria is uniquely prepared to lead in the delivery of emerging new mental health therapies. Emyria's Pax Centre has the specialist oversight, multidisciplinary team and state-of-the-art facilities to deliver and evaluate MDMA-AT (and other psychedelic-assisted therapies) at scale. Emyria's unique model offers several advantages for patients and investors:

- **Wraparound Care:** Emyria's clinics offer comprehensive patient support ensuring personalised care is available before, during and after any innovative therapy.
- **Data-Driven:** Routine data capture allows for continual refinement of treatments and supports Emyria's drug development programs.
- **Diversified Revenue Streams:** A balance between immediate clinical service revenues and the long-term potential of drug development offers investors stability and growth.

Dr. Jon Laugharne, Emyria's lead psychiatrist, commented: *"For individuals grappling with PTSD, the current treatment landscape can feel limiting. By initiating active MDMA-assisted therapy within an operational private clinic, as opposed to traditional academic settings, we aim to prioritise Real-World patient well-being and learning in order to develop a viable delivery model that can scale."*

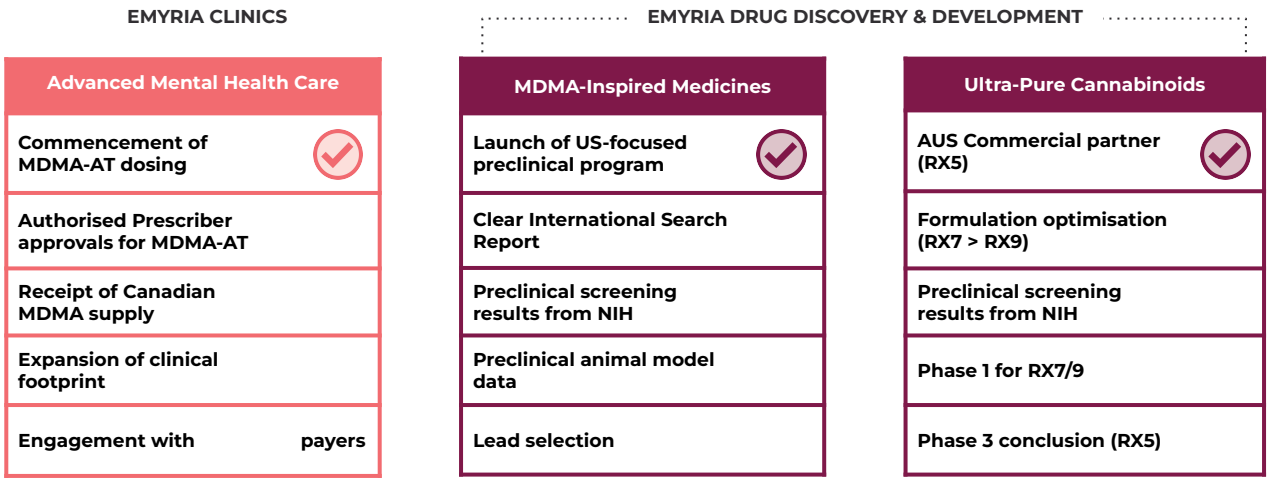
Emyria's Initial Target Indication: PTSD

With PTSD affecting approximately 1 million Australians [2], there is a growing need for more effective treatments. MDMA-AT is showing promise as a treatment for PTSD in multiple Phase 3 clinical trials conducted by MAPS in the USA. [1, 3] Emyria's MDMA-AT trial aims to provide vital Real-World Data and insights to support the launch of Emyria's Authorised Prescriber program, engage payers and inform how Emyria's model can scale in a commercially viable manner.

EMDMA-001 Trial Details

ITEM	DESCRIPTION
Primary Endpoint(s)	Safety and cost effectiveness measures.
Secondary Endpoint(s)	Comprehensive suite of clinical and quality of life measures.
Product Status	MDMA has been recently rescheduled to a Schedule 8 controlled medicine for the treatment of PTSD. The MDMA used in the study is an unregistered GMP-grade medicine (i.e. "pharmaceutical quality"). There are no approved MDMA medications.
Treatment Method, Route, Frequency, Dose Levels, Expected Duration	Participants will receive up to three MDMA-assisted therapy sessions over three months and followed up for 12 months post treatment. Treatment sessions will be supplemented by extensive preparation and integration sessions before, during, and after.
Number of Trial Subjects & Selection Criteria	The trial is designed with no maximum number of participants. Emyria has secured sufficient MDMA supply for an initial cohort of up to 70 adult participants, all of whom have been diagnosed with PTSD.
Trial Locations	The trial will take place at Emyria's Pax Centre but it is possible to add additional sites once suitably prepared.
Trial Standard	The study is being conducted in accordance with international best practice standards and fully complies with the principles of Good Clinical Practice (**GCP**), as outlined by the International Council for Harmonisation (**ICH**).

RECENT TRACTION & UPCOMING MILESTONES



References:

1. Mitchell, J.M., et al. MDMA-assisted therapy for moderate to severe PTSD: a randomized, placebo-controlled phase 3 trial. Nat Med (2023)
2. https://www.phoenixaustralia.org/
3. Mitchell, J.M., et al. MDMA-assisted therapy for severe PTSD: a randomized, double-blind, placebo-controlled phase 3 study. Nat Med 27, 1025–1033 (2021)

This release has been approved by the Board of Emyria.

FOR FURTHER INFORMATION

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Emyria Limited is a clinical services and drug development company focused on revolutionising patient outcomes in neuroscience and mental health via a unique business model:

generates

Emyria Clinics: Deliver evidence-based and emerging therapies for mental health and other unmet needs across multiple sites (Emerald Clinics and The Pax Centre)

Emyria Data: Robust and ethically-sourced Real-World Data gathered with patients and integrated into an advanced data platform powered by Palantir. Emyria data is used to improve Emyria's distinct therapy and drug development programs.

informs

Emyria Drug Discovery: One of the world's largest libraries of unique MDMA-like compounds developed in partnership with the University of Western Australia seeking new psychedelic-assisted therapies and treatments for neuropsychiatric disease.
Emyria Drug Development: A suite of unique, highly potent dose forms of Ultra-Pure cannabinoids seeking registration for a range of mental health and neuroscience indications.

EMYRIA'S INTERACTIVE INVESTOR HUB
Investorhub.emyria.com Interact with Emyria's announcements and updates by asking questions and comments, which our team can respond to where possible.

paxcentre.com.au

The Pax Centre specialises in treating individuals grappling with the psychological impacts of traumatic experiences. Our treatment approach is highly personalised, addressing a wide range of mental health issues, from PTSD and depression to anxiety disorders and substance abuse, often stemming from various life traumas.

Complex trauma, characterised by repeated, relational traumatic events often occurring during developmental stages, requires specialised attention due to its pervasive and lasting impact. In these cases, The Pax Centre prioritises early diagnosis and evidence-based treatments.

We also focus on proactive strategies for health expansion and personal growth, empowering our clients with skills and tools to improve wellbeing and performance. At the Pax Centre, we believe in transforming lives through focused, evidence-based mental health care.

emeraldclinics.com.au

Emerald Clinics is an Australian-based, patient-centric clinical service specialising in providing treatments for patients with complex and chronic conditions, where traditional therapies might not have yielded satisfactory results.

Leveraging our deep expertise with unregistered medicines, such as cannabinoids, we strive to pioneer and personalise care for our patients. Our robust, ethically-sourced data collection methods underpin our commitment to improving patient outcomes and advancing healthcare innovation.

CAUTIONARY NOTE ON FORWARD-LOOKING STATEMENTS Any statements in this press release about future expectations, plans and prospects for the Company, the Company's strategy, future operations, and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the Company's ability to successfully develop its product candidates and timely complete its planned clinical programs and the Company's ability to obtain marketing approvals for its product candidates. In addition, the forward-looking statements included in this press release represents the Company's views as of the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.