ASX Announcement
19 Oct 2023

emyria

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

Health Canada Approval Received for MDMA Import

HIGHLIGHTS

- Emyria to commence importation of MDMA into Australia after receiving notification that all Health Canada export permits have confirms all regulatory requirements met/completed
- The approval follows the start of active dosing in Emyria's ethics-approved MDMA-assisted therapy ('MDMA-AT') trial earlier this month [1]
- The initial supply of MDMA can support Emyria's MDMA-AT program for up to 70 patients
- 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 [2]

Emyria Limited (ASX: EMD) ("Emyria", or the "Company") has been notified that all necessary regulatory permits have been received from Health Canada to start the importation of Emyria's patient-ready MDMA supply secured in February.[3] This significant development follows the start of dosing for Emyria's MDMA-assisted therapy program, believed to be a first for a private specialist clinic in Australia. [1] Having secured the necessary approvals from Australia's Office of Drug Control ('ODC') — which stringently oversees the importation of unapproved medications — the Health Canada approval completes the regulatory pathway and allows Emyria to commence importation.

What will the MDMA be used for?
Emyria's MDMA supply is sufficient for up to 70 patients and is pivotal for both our active ethics-approved MDMA-assisted therapy trial ('EMDMA-001') and, potentially, direct patient care if our specialists receive Authorised Prescriber ('AP') status from the TGA. Currently, our AP applications await ethics committee review, with subsequent TGA approval also required.

Emyria's Initial Target Indication: Post-Traumatic Stress Disorder ('PTSD')
PTSD affects approximately 1 million Australians. [4] There is a growing need for more effective treatments and MDMA-AT is showing promise in multiple Phase 3 clinical trials conducted by MAPS in the USA. [2, 5] Emyria's MDMA-AT trial aims to provide vital Real-World Data and insights to help guide Emyria's planned Authorised Prescriber program, help engage payers and inform how Emyria's model could scale in a commercially viable manner.

What is the role of the EMDMA-001 trial?
The EMDMA-001 trial serves as the foundation for Emyria's 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. Emyria's trial strengthens its AP application while also generating robust clinical evidence to support payer engagement and Emyria's novel drug development programs. A successfully initiated AP program for MDMA-AT could broaden access to Emyria's innovative services for suitably assessed patients.

Emyria CEO, Dr Michael Winlo said, *"As a leading private specialist clinic in Australia, we've achieved a significant milestone with the initiation of active MDMA-assisted therapy. Our initial MDMA supply for up to 70 patients, combined with our steady progress towards Authorised Prescriber status, underscores our commitment to exploring promising treatments for PTSD sufferers and elevating mental health care outcomes in Australia."*

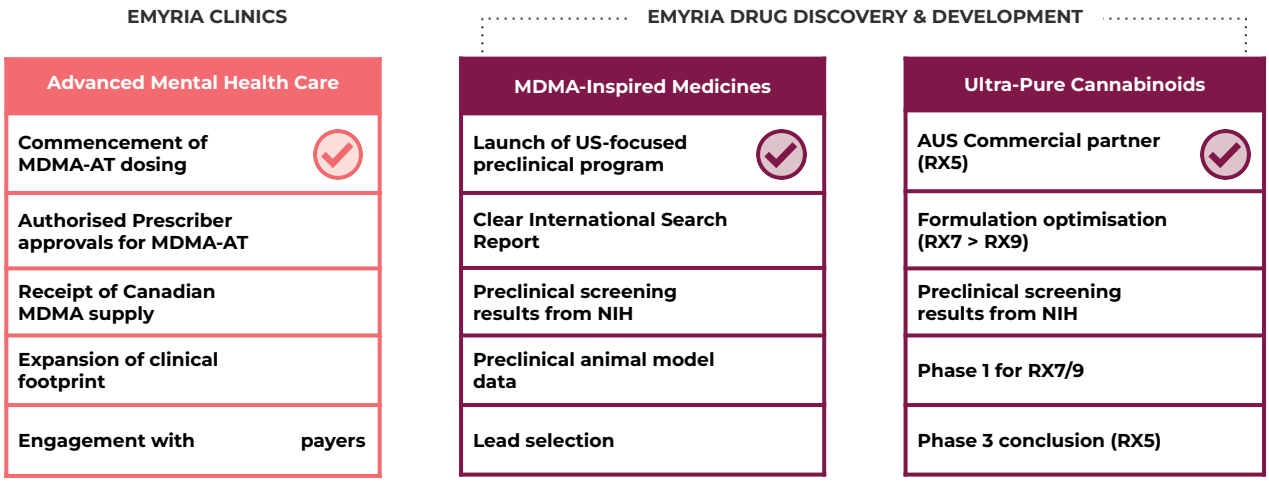
Emyria's unique care model provides specialist oversight, a multidisciplinary team and state-of-the-art facilities to deliver and evaluate MDMA-AT (and other psychedelic-assisted therapies) at scale with several advantages for patients and investors:

- **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 patient monitoring, 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.

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. See ASX release 09 October 2023
2. Mitchell, J.M., et al. MDMA-assisted therapy for moderate to severe PTSD: a randomized, placebo-controlled phase 3 trial. Nat Med (2023)
3. See ASX release 13 February 2023
4. https://www.phoenixaustralia.org/
5. 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 **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.

emerald clinics **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.