ASX Announcement
21 Sep 2023

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

Emyria Secures Local MDMA to Start PTSD Trial Dosing

HIGHLIGHTS

- Emyria has secured a supply of locally-available MDMA, pivotal for initiating dosing for its ethics approved MDMA-assisted therapy ('MDMA-AT') trial.
- Results from a second Phase 3 clinical trial released last week by MAPS underscore the efficacy of MDMA-assisted therapy for Post-Traumatic Stress Disorder ('PTSD'). [1]
- Recent acquisition of the Pax Centre prepares Emyria with a unique combination of specialist oversight, state-of-the-art facilities, and data capture capabilities to deliver and evaluate MDMA-AT. [2]
- Emyria to provide essential data to the national patient registry led by the Australian National University ('ANU'). [3]

Emyria Limited (ASX: EMD) ("Emyria", or the "Company") is pleased to announce it has secured a locally-available supply of MDMA through a collaboration with Mind Medicine Australia ('MMA') and the Australian National University ('ANU'). This supply ensures the timely commencement of Emyria's ethics-approved MDMA-assisted therapy ('MDMA-AT') trial (EMDMA-001) while awaiting a comprehensive shipment from Canada.

Dr. Michael Winlo, CEO of Emyria, commented: *"With our recent milestones, including the Pax Centre acquisition [2], our team's training, and ethics approval [4], MDMA supply was the final component. We are grateful to MMA and the ANU for their support in securing an immediately available initial supply which ensures we can continue progress while we wait for our subsequent larger shipment from Canada pending approval from Health Canada. [5]"*

The call for more effective PTSD treatments in Australia is underlined by compelling statistics. Approximately 1 million Australians develop PTSD annually, with around 400,000 potentially suitable for MDMA-AT. [6]

Recently released results from a second Phase 3 clinical trial on MDMA-AT for PTSD undertaken by the Multidisciplinary Association for Psychedelic Studies ('MAPS') [1] further affirm the treatment's potential and the outcomes of the first trial disclosed in May 2021 [7]:

- **86.5%** of participants in the MDMA therapy group noted improved symptoms.
- **71.2%** of participants no longer met the criteria for PTSD following treatment.
- A significant portion of the second study participants were from diverse backgrounds illustrating the broader generalisability of the treatment.
- Reported side effects of the treatment, including muscle tightness and nausea, were in line with expectations, and challenges like suicidal ideation were observed at rates comparable to the placebo group.

The proactive regulatory environment in Australia, combined with Emyria's readiness, places the Company in a favourable global position.

Emyria's recent acquisition of the Pax Centre underscores the Company's dedication to comprehensive patient-centred care. Emyria's broader mental health footprint combined with the Company's capabilities in robust data capture and research excellence positions the Company to lead in both clinical delivery and drug development. Central to Emyria's mission is the belief in the importance of data-driven insights to shape the future of healthcare.

The School of Medicine at the Australian National University is spearheading a novel patient registry in Australia. [3] This registry aims to gauge the effectiveness and safety of psychedelic substances when used therapeutically for severe mental health conditions, including depression and post-traumatic stress disorder (PTSD). It will aggregate and analyse real-world data from clinical practice involving MDMA and psilocybin. Emyria is committed to contributing to this work and anticipates that the trial results from EMDMA-001 will offer crucial insights to the registry and set a benchmark for future studies.

Professor Paul Fitzgerald, from the ANU School of Medicine and Psychology, said; *"Australia's approach to regulated psychedelic use is unique and forward-thinking. Our collaboration with Emyria will help us to expand our knowledge base, capturing insights beyond the controlled environment of clinical trials. This partnership aims to deepen our understanding of the real-world impact of these therapies."*

Chair and Co-Founder of Mind Medicine Australia [8], Peter Hunt AM, stated, *"A primary mission at MMA is to catalyse and support research into the potential of psychedelic medicines to address unmet needs in mental health treatments. We're pleased to assist Emyria and believe that collaborative efforts like these position Australia at the forefront of global advancements in mental health research."*

Timeline of Key Events:

13 February 2023

Emyria executes MDMA supply agreement with PharmAla

Emyria secures MDMA for ~70 patients. Import process to commence once Australia's Office of Drug Control (ODC) provides approval for importation.

08 June 2023

Emyria receives Ethics Approval for MDMA-assisted therapy trial (EMDMA-001)

Ethics approval allows Emyria to apply for import permit from the ODC.

12 July 2023

Emyria Australia's Office of Drug Control (ODC) approves importation of MDMA from Canada

Import permit provided to Health Canada. Now waiting for approval from Health Canada in order to commence export of MDMA into Australia.

21 September 2023

Emyria secures a local-source of MDMA to allow dosing commencement for MDMA-AT trial

While waiting for Health Canada approval, Emyria obtains locally-available MDMA to allow patient dosing to commence for Emyria's ethics approved trial, noting there is no guarantee that Emyria will be able to obtain approval from Health Canada

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RECENT TRACTION & UPCOMING MILESTONES

CLINICAL DELIVERY

Advanced mental health care
Acquisition of leading psychological trauma service ✓
Commencement of MDMA-assisted therapy ✓
Expand treatment offerings ✓
Authorised Prescriber approvals
Expansion of clinical footprint
Engagement with payers
Leverage data platform

THERAPY DEVELOPMENT

MDMA-inspired Medicines
First patent family filed ✓
US-focused preclinical program ✓
Metabolic studies ✓
Preclinical animal models ✓
Lead selection
Phase 1 trials
Global commercial strategy

Ultra-Pure Cannabinoids
Preclinical Screening Program for Pain (RX7) ✓
Formulation optimisation (RX7 > RX9) ✓
AUS Commercial partner (RX5) ✓
US Commercial partners
Phase 3 conclusion (RX5)
Phase 1 (RX7 & RX9)
FDA Pre-IND (RX7 & RX9)

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. See ASX release 13 September 2023
3. https://reporter.anu.edu.au/all-stories/registry-to-inform-use-of-psychedelic-based-therapy-for-depression-and-ptsd
4. See ASX release 08 June 2023
5. See ASX release 13 February 2023
6. See Emyria Company Update 06 September 2023
7. 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)
8. Mind Medicine Australia (MMA) is a registered charity set up to develop the ecosystem in Australia so that psychedelic-assisted therapies can become an available option for patients suffering from key classes of mental illness. https://mindmedicineaustralia.org.au/

This release has been approved by the Managing Director of Emyria.

FOR FURTHER INFORMATION

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ABOUT EMYRIA | emyria.com

- **Emyria Limited** is a clinical services and drug development company with a focus on revolutionising patient outcomes in neuroscience and mental health via:
  - **Clinical Service Delivery:** With Emerald Clinics, and the recent acquisition of the Pax Centre, a leading psychological trauma center, Emyria delivers evidence-based and emerging therapies for mental health and other unmet needs.
  - **Proprietary Real-World Data (RWD):** Through its advanced data platform powered by Palantir, Emyria collects robust and ethically-sourced Real-World Data to improve its care models and support its distinct therapy and drug development initiatives.
  - **Drug Discovery & Development:** Guided by its RWD, Emyria is developing several proprietary Ultra-Pure cannabinoid dose forms and advancing them towards registration. In parallel, we are establishing one of the world's largest libraries of MDMA-like compounds in partnership with the University of Western Australia.

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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.

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ABOUT The Pax Centre | paxcentre.com.au

PaxCentre

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

ABOUT Emerald Clinics | emeraldclinics.com.au

emerald clinics

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.