ASX Announcement
08 Jun 2023

emyria

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

Emyria receives ethics approval for MDMA-assisted therapy

PaxCentre

HIGHLIGHTS

Emyria receives Human Research Ethics Committee (HREC) approval to commence a pivotal MDMA-assisted therapy trial (EMDMA-001) for Post-Traumatic Stress Disorder with partners, the PAX Centre

PAX Centre is one of **Australia's leading trauma-focused, multidisciplinary psychiatric services** specialising in the treatment of complex trauma [1]

Emyria's MDMA-assisted therapy trial **will support the development of**:

- **Best-practice protocols** for safe, community-based delivery of MDMA-assisted therapy
- **Authorised Prescriber** applications for Emyria-network psychiatrists from July 1st
- **Cost effectiveness** evaluations to support payer engagement and commercialisation
- **Real World Data** collection methods to support safety and care model improvement

Therapist training is completed for 20 psychiatrists, GPs, mental health nurses, clinical psychologists and counsellors by renowned psychiatrist and psychedelic-assisted therapy researcher, **Dr. Ben Sessa** [2]

Pharmaceutical-grade MDMA has been secured [3]; Importation process has commenced

Emyria will now **develop care models for psilocybin-assisted therapy**

Emyria Limited (ASX: EMD), a clinical stage biotech and medical services provider (Emyria or the Company), is pleased to announce is has received Human Research Ethics Committee approval to conduct its proposed twelve-month, open-label, single centre MDMA-assisted therapy clinical trial (EMDMA-001) for patients with Post-Traumatic Stress Disorder (PTSD).

PTSD is a significant mental health issue in both the United States and Australia. In the US, approximately 10 million people are estimated to suffer from PTSD with total excess economic burden costs estimated to be around $232.2 billion per year. [4]

In Australia, approximately 1 million people suffer from PTSD. 30-50% of patients have an ineffective response or resistance to standard therapies. There is an increasing urgent need for more effective therapies. [5]

MDMA-assisted therapy has shown promising results for patients with PTSD [6,]
Until the TGA announcement its use has been limited to research settings requiring extensive restrictive protocols limiting its use to trial patients.

Emyria's Managing Director, Dr Michael Winlo said: *We're excited to announce the recent ethics approval for Emyria's MDMA-assisted therapy trial for PTSD. This pivotal step, made possible by our partnership with The Pax Centre, highlights our commitment to advancing new psychiatric care. Our joint endeavor aims to deliver a safe, cost-effective, and scientifically grounded approach to PTSD treatment that can support the development of cost-effective and scalable MDMA-assisted therapy delivery in the community.*

This trial is expected to improve patient outcomes in a safe environment and generate valuable Real World Data, allowing program improvements and furthering Emyria's drug analogue development. For our investors and shareholders, this represents a significant milestone and growth opportunity in the burgeoning field of psychedelic-assisted therapy."

Starting from July 1st, 2023, the TGA has changed the classification that will enable patient access to MDMA-assisted therapy as a Schedule 8 controlled medicine [7] . This is via prescription from specialist psychiatrists who have obtained "Authorised Prescriber" status. The Royal Australian and New Zealand College of Psychiatrists have required that, *"prescribing psychiatrists must demonstrate adequate training, evidence-based treatment protocols, patient selection, and monitoring to be approved to prescribe this therapy. Ongoing psychotherapeutic support is also essential for this treatment model."* [8]

It is anticipated that only a small number of psychiatrists with first-hand experience working with psychedelic-assisted therapies in clinical trials will meet the requirements for Authorised Prescriber status.

Emyria's licensable package, combining a robust, ethics-approved care model and reliable drug supply, [3] **has been developed to support Authorised Prescriber (AP) applications from Emyria-network psychiatrists from July 1st.** It is anticipated that "Emyria-network APs" supported by a trained, multidisciplinary team, will be some of the first specialists able to offer psychedelic-assisted therapy as a commercially viable service for suitably screened patients.

To support this vision, Emyria draws upon extensive experience in prescribing unregistered treatments at Emerald Clinics, care model design and Real World Data capture. By applying Emyria's well-established, data driven approach to the emerging field of psychedelic-assisted therapies, the Company believes it can help its healthcare provider partners enhance their service offering and improve the lives of Australian patients diagnosed with PTSD and treatment-resistant depression.

Emyria sees the establishment of a comprehensive and multidisciplinary provider network as a commercially viable pathway to further its mission. By fostering a mutually beneficial ecosystem, Emyria is extending its clinical offerings and facilitating safe patient access to innovative treatments. The proprietary Real-World Data gathered also underpins the Company's novel drug development programs.

The clinical data generated in this trial will support ongoing care model improvements, crucial cost-effectiveness studies to support reimbursement, and also Emyria's active MDMA-inspired drug development program with partner the University of Western Australia.

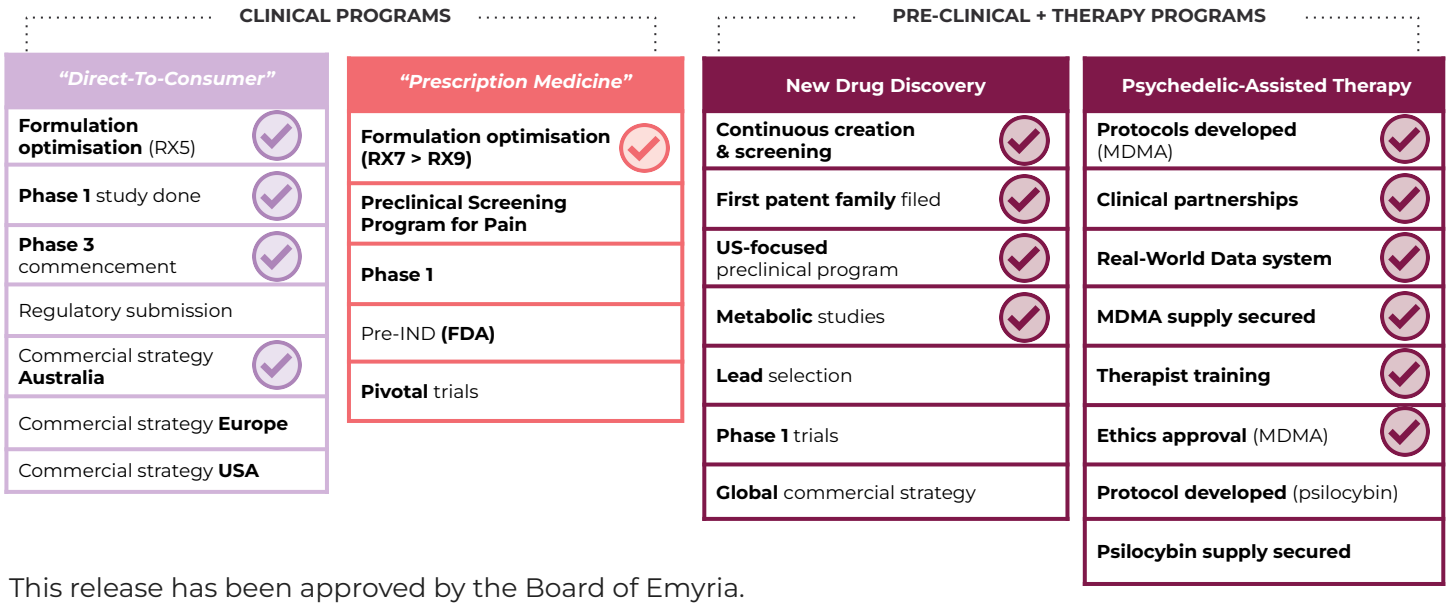
Emyria's novel, MDMA-inspired drug discovery program is seeking to create new medicines. Current, leading programs are focussed on:

- Faster acting MDMA-like compounds with the potential to shorten treatment session times and increase the number of patients treated and;
- A novel therapy to ameliorate the symptoms of Parkinson's disease treatment.

The recent rescheduling of MDMA by the TGA further supports Emyria's novel MDMA-inspired drug development program by opening a pathway to registration and reimbursement for these novel compounds across a range of neuropsychiatric disorders.

Emyria is advancing its drug discovery program in Australia and the United States to identify novel, MDMA-like compounds with therapeutic potential, while collaborating with local clinical partners to improve patient access and ongoing research.

RECENT TRACTION & UPCOMING MILESTONES



This release has been approved by the Board of Emyria.

FOR FURTHER INFORMATION

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1. https://www.paxcentre.com.au/our-story
2. http://www.drsessa.com/specialist-psychopharmacology-research/
3. See ASX release 13 Feb 2023
4. Davis LL, Schein J, Cloutier M, et al. The economic burden of posttraumatic stress disorder in the United States from a societal perspective. J Clin Psychiatry. 2022;83(3):21m14116
5. https://www.phoenixaustralia.org/
6. Mitchell, J.M., Bogenschutz, M., Lilienstein, A. et al. MDMA-assisted therapy for severe PTSD: a randomized, double-blind, placebo-controlled phase 3 study. Nat Med 27, 1025–1033 (2021)
7. https://www.tga.gov.au/sites/default/files/2023-02/notice-of-final-decision-to-amend-or-not-amend-the-current-poisons-standard-june-2022-acms-38-psilocybine-and-mdma.pdf accessed 05 Feb 2023
8. https://www.ranzcp.org/news-policy/news/change-to-classification-of-psilocybin-and-mdma

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:** 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) and partners. Emyria RWD can help support drug development and care model improvement.

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.

ABOUT PAX Centre | paxcentre.com.au

The Pax Centre ('PAX') provides expert assessment and treatment for those suffering from the psychological impact of traumatic life experiences.

PAX offers an individualised approach to assessing and treating people suffering from the effects of traumatic life experiences. Such experiences can result in various mental health problems including post-traumatic stress disorder (PTSD), complex PTSD and dissociation, depression, other anxiety disorders, chronic adjustment reactions, somatic syndromes and abuse of alcohol or drugs.

Traumatic experiences can include a wide range of life events, such as physical or sexual assault, natural disasters, medical procedures, sudden bereavements or wartime incidents. Whilst most people can, and do, recover from such experiences with the support of family and friends, some will develop significant problems which can have a major effect on their day-to-day lives, often affecting their work and relationships.

Complex trauma differs from single-incident trauma in that it is a multifaceted syndrome where the traumatic event(s) were relational, repeated, and cumulative; and it usually occurs at developmentally sensitive stages of neurological maturation. For this reason, the social, emotional, behavioural and interpersonal effects of childhood trauma are often pervasive and continue to affect many different areas of people's adult lives long after the original trauma has passed and/or been debriefed. PAX have found that when these situations arise, an early assessment, diagnosis and the initiation of appropriate evidence-based treatment strategies is vital.

In addition to this, PAX teach proactive, preventative and health expanding strategies to enable the personal growth, improved well-being and performance of our clients. Empowering PAX clients through the acquisition of new skills and tools is the focus of our philosophy.

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.