

ASX Announcement

07 Mar 2023



Emyria partners with specialist trauma psychiatric service to advance MDMA-assisted therapy

HIGHLIGHTS

Emyria and PAX Centre to develop a scalable MDMA-assisted therapy model for patients with complex PTSD

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

Collaboration is part of Emyria's longer-term goal to establish a network of trained therapists and psychiatrists to provide MDMA-assisted therapy - via ethics approved clinical trials and the Authorised Prescriber pathway - to appropriately diagnosed patients from July 1st 2023

Emyria Limited (ASX: EMD), a clinical stage biotech company, has announced a collaboration with The Pax Centre (PAX), Australia's leading multidisciplinary, psychiatrist-led clinical service specialising in complex trauma treatment.

The collaboration aims to develop a scalable care program for the safe provision of MDMA-assisted therapy, in the community, for patients with treatment resistant PTSD.

PAX will provide specialist psychiatrists, trained therapists, and facilities. Emyria will manage clinical trial design, Real-World Data generation, data monitoring and MDMA supply following the recent securing of patient-ready MDMA. ^[1] The care program will commence as an ethics-approved clinical trial (with Emyria as Sponsor) until PAX psychiatrists have obtained Authorised Prescriber status and a cost model has been developed. The care program could support other specialist groups under licence.

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. ^[2]

In Australia, approximately 1 million people are estimated to suffer from PTSD. Given around 30-50% of PTSD patients show resistance to standard treatment there has been increasing interest in novel treatment approaches. ^[3]

MDMA-assisted therapy has shown promising results for patients with PTSD ^[4] but its use has been limited to research settings due to the extensive preparations required encompassing therapist training, clinical protocol design, facility preparation, data monitoring, and drug supply coordination.

Emyria's Managing Director, Dr Michael Winlo said: *"As the burden of PTSD grows, the interest and demand for new treatment options increases amongst patients and specialists."*

Following the TGA's recent decision to reschedule MDMA to a controlled medicine, we believe the demand amongst psychiatry groups for a safe, cost-effective, and evidence-based care program to deliver MDMA-assisted therapy in the community for suitably screened patients.

Emyria is thrilled to collaborate with The Pax Centre, a leading psychiatric clinical service, to develop this care program. Our team looks forward to developing clinical protocols with their experts that may help patients with PTSD while generating Real World Data that can support ongoing program improvement as well as Emyria's novel drug development program."

Starting from July 1st, 2023, the TGA's Authorised Prescriber Program in Australia

will allow patient access to MDMA-assisted therapy as a Schedule 8 controlled medicine ^[5]. However, as stated by the Royal Australian and New Zealand College of Psychiatrists, *"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."* ^[6]

Emyria's partnership with PAX aims to directly address these challenges by developing a scalable care program for MDMA-assisted therapy that can be safely and cost-effectively administered to patients with PTSD through community psychiatry groups. Emyria will develop the clinical delivery and data monitoring protocols while PAX will provide specialists and trained therapists, and an appropriate facility to administer the therapy safely.

Emyria has already secured a supply of patient-ready MDMA ^[1]

Emyria believes a comprehensive clinical package (eg program + drug supply) has the potential to be licensed to other specialist groups wishing to participate in the network to help support the nearly 500,000 Australian patients with treatment-resistant PTSD.

PAX Centre Director, Psychiatrist Dr Jon Laugharne said: *"Caring for patients with complex trauma can be incredibly challenging, and we have had to close our books to new patients due to both the size of the problem and the relatively low remission rates with current treatments."*

Working in this space is complex, with so many unknowns, but we are pleased to have the support of Emyria to help us navigate these challenges and bring this exciting and innovative treatment to those patients who need it most."



PAX Centre Director, Mental Health Nurse Claire Kullack said:

"This collaboration strongly aligns with our mission to provide the best possible care and outcomes for our patients and to continually seek out and adopt new, evidence-based treatments."

As one of the leading services tackling complex trauma in Australia, we have always prided ourselves on being at the forefront of innovative and multidisciplinary approaches to care. We are excited to partner with Emyria to explore the feasibility of this promising new treatment option for our patients with PTSD."

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The Real World Data to be generated in this partnership 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 looking to create new medicines, and currently, leading programs are working on the following:

- Faster acting MDMA-like compound 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.

UPCOMING MILESTONES

CLINICAL PROGRAMS		PRE-CLINICAL + THERAPY PROGRAMS	
"direct-to-consumer"	"prescription medicine"	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

FOR FURTHER INFORMATION

This release has been approved by the Board of Emyria.

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1. See ASX release 13 Feb 2023
2. 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
<https://www.phoenixaustralia.org/>
3. 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)
4. <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
5. <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). Emyria RWD can help support drug development and care model improvement.

EMYRIA'S INTERACTIVE INVESTOR HUB

[Investorhub.emyria.com](https://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.