



**ASX Announcement**  
18 Apr 2023

**emyria**

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

## **Psilocybin-Assisted Therapy Care Model to be developed by Emyria and PAX Centre**



### **HIGHLIGHTS**

**Emyria and PAX Centre to develop a care model for psilocybin-assisted therapy** in addition to their existing **MDMA-assisted therapy care model**

**Collaboration aims to address substantial overlap between symptoms of depression and PTSD** - conditions with growing prevalence - by expanding treatment offerings available for patients with either or both conditions

**Dr. Ben Sessa, internationally renowned psychiatrist**, MDMA researcher and recently appointed teaching faculty at Mind Medicine Australia, engaged to provide therapist training across MDMA and psilocybin

Emyria aims to establish a network of trained therapists and psychiatrists to provide MDMA-assisted therapy to appropriately diagnosed patients from July 1st, 2023, through ethics-approved clinical trials and the Authorised Prescriber<sup>[1]</sup> pathway

Collaborating with psychiatrist-led medical practices improves patient safety and enables the collection of Real-World Data which supports ongoing care innovation and drug development.

**Emyria Limited (ASX: EMD)**, (Emyria or the Company) a clinical-stage biotech company, and PAX Centre - a leading psychiatrist-led medical practice, are pleased to extend their collaboration and develop a care model for psilocybin-assisted therapy. The addition of a psilocybin-assisted therapy model will complement their existing MDMA-assisted therapy care model, addressing the substantial overlap between symptoms of post-traumatic stress disorder (PTSD) and major depression.<sup>[2]</sup>

**Emyria and PAX Centre** are committed to addressing the growing prevalence of PTSD and depression, affecting millions worldwide. With the Therapeutic Goods Administration (TGA) in Australia restricting the use of MDMA for PTSD and psilocybin for major depression from July 1st, 2023, this collaboration aims to create a comprehensive and innovative care option for suitably screened patients suffering from either or both conditions.

To ensure **the highest level of therapist training**, Emyria and PAX Centre - with the **support of Mind Medicine Australia** - have engaged **Dr Ben Sessa, a prominent psychiatrist** and MDMA researcher. With over 20 years of experience in psychiatry and a strong background in MDMA-assisted psychotherapy, Dr Sessa will provide valuable expertise and training support.

**Dr Sessa is one of only a few clinicians who have facilitated psychedelic-assisted therapy sessions with patients using MDMA, psilocybin and ketamine**, making him a respected authority in the field. Dr Sessa has also been recently appointed to the faculty of Mind Medicine Australia to assist with their therapist training program.

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Similar to the MDMA-assisted therapy model recently developed, 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 will work on securing patient-ready psilocybin.**

**Emyria's Managing Director, Dr Michael Winlo said:** *"We are excited to extend our collaboration with the experienced trauma specialists at the PAX Centre to develop a psilocybin-assisted therapy model for major depression to complement our MDMA-assisted therapy that is already well advanced. The generalist training provided by Dr. Ben Sessa supports our mission to create innovative and effective mental health care models within community psychiatry as well as supports our goal to generate high quality clinical data".*

**PAX Centre Director, Psychiatrist Dr Jon Laugharne said:** *"As a specialist centre for complex trauma, PAX Centre understands the intricacies of treating patients with PTSD, and we often see patients who are also suffering from depression. These co-occurring conditions present unique challenges, and we are hopeful that our collaboration with Emyria and the training support of Dr. Ben Sessa, will help us provide more comprehensive and evidence-based care for our patients."*



In addition to developing the psilocybin-assisted therapy care model, Emyria and PAX Centre have made progress on their MDMA-assisted therapy program. **The team has successfully secured a supply of patient-ready MDMA,**<sup>[3]</sup> and the important process has commenced. The care plan has been completed, and preparations are now underway at the facility to accommodate the unique requirements of MDMA-assisted therapy. The upcoming training sessions led by Dr Ben Sessa, an expert in the field, will help equip the experienced staff with the knowledge and skills necessary to provide the highest standard of care.

The collaboration between Emyria and PAX Centre, a psychiatrist-led medical practice, **ensures enhanced patient safety and the highest standards of care**, as all patients will be known to the clinic. Emyria will leverage its data capture expertise to gather Real World Data to guide ongoing care model innovation, therapy reimbursement discussions with payers and novel drug development.

## About Dr Ben Sessa

Dr Ben Sessa is a highly respected and experienced Consultant Psychiatrist with expertise in child and adolescent mental health. He has been working in psychiatry since 1997, and his clinical practice spans the UK National Health Service (NHS) and the private sector. Dr Sessa is also deeply involved in psychedelic research, focusing on the potential therapeutic applications of MDMA, psilocybin and ketamine for treating various psychiatric disorders.

As a researcher and writer, Dr Sessa has authored several books and scientific papers, including his acclaimed book "The Psychedelic Renaissance." He co-founded the Breaking Convention conference and is an advisor to the All-Party Parliamentary Group for Drug Policy Reform. Dr Sessa is dedicated to promoting safe and evidence-based psychedelic therapies and regularly presents his work at international conferences and seminars.

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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<sup>[4]</sup> 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	
<i>"direct-to-consumer"</i>		<i>"prescription medicine"</i>	
Formulation optimisation (RX5) ✓	Formulation optimisation (RX7) ✓	<b>New Drug Discovery</b>	<b>MDMA-assisted therapy</b>
Phase 1 study done ✓	Phase 1	Continuous creation & screening ✓	Protocol developed ✓
Phase 3 commencement ✓	Pre-IND (FDA)	First patent family filed ✓	Clinical partnerships ✓
Regulatory submission	Pivotal trials	US-focused preclinical program ✓	Real-World Data system ✓
Commercial strategy <b>Australia</b> ✓		Metabolic studies ✓	MDMA supply secured ✓
Commercial strategy <b>Europe</b>		Lead selection	Therapist training ✓
Commercial strategy <b>USA</b>		Phase 1 trials	First patient
		Global commercial strategy	Global commercial strategy

This release has been approved by the Board of Emyria.

## FOR FURTHER INFORMATION

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1. <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
2. Aspesi, Dario & Pinna, Graziano. (2018). Could a blood test for PTSD and depression be on the horizon?. Expert Review of Proteomics. 15. 10.1080/14789450.2018.1544894. See ASX release 13 Feb 2023
3. See ASX release 13 Feb 2023
4. <https://www.ranzcp.org/news-policy/news/change-to-classification-of-psilocybin-and-mdma>

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## ABOUT EMYRIA | [emyria.com](https://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](https://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.