



Emyria Launches Ketamine-Assisted Therapy Program at Pax Centre; Dr. Ben Sessa Appointed Scientific Advisor

HIGHLIGHTS

Ketamine's Potential: Recent Australian studies spotlight ketamine as a groundbreaking treatment for severe depression, with notable symptom reduction in participants.¹

Integrated Approach: Emphasising the importance of coupling ketamine with structured psychotherapy, Emyria is developing a pioneering ketamine-assisted therapy (KAT) program at subsidiary, The Pax Centre.

Dr. Ben Sessa's Role: Having supervised over 100 KAT sessions Dr. Ben Sessa will help develop unique protocols for Emyria that combine ketamine with integrative psychotherapy for a range of mental health challenges.

Emyria's Unique Position: Emyria's KAT offering is expected to increase options for patients, service revenues and data insights and reinforce Emyria's commitment to become a global leader in the development and delivery of promising, emerging mental health treatments.

Emyria Limited (ASX: EMD) (Emyria, or the **Company**) is pleased to announce the launch of its unique ketamine-assisted therapy (KAT) program, strategically located at the Pax Centre, and with support from newly appointed Scientific Advisor, Dr. Ben Sessa.

Recent Australian research unveils the potential of ketamine as a promising treatment for severe and treatment-resistant depression.¹ Results from these studies showcase a significant proportion of participants achieving remission or notable reductions in depressive symptoms following a month-long regimen of ketamine injections. However, the therapeutic benefits seem to wane post-discontinuation, indicating the potential need for sustained or periodic treatment to maintain its antidepressant impact.

While the comprehensive therapeutic framework for delivering ketamine is still evolving, emerging trials also highlight the essential role of providing structured psychological therapy alongside ketamine treatment for improving the durability of treatment.²

Guided by these insights, and having recently undergone extensive preparations for MDMA-assisted therapy, Emyria is developing a KAT program to run within the Pax Centre under the guidance of Dr. Ben Sessa, who has directly overseen more than 100 KAT sessions. Emyria's KAT program will initially target treatment resistant depression through a course of generic ketamine either intramuscularly or subcutaneously paired with a personalised program of attentive psychotherapy. Patients will pay out of pocket for a package of drug treatment and therapy. Given generic ketamine currently costs about \$5 per dose, (compared to proprietary formulations that can cost \$800 a dose²) the program is expected to measure and deliver strong cost effectiveness through Emyria's Real World Data tracking. The Emyria KAT program is anticipated to become a set of protocols that can be licensed to other providers wishing to offer the same service.

"I am deeply committed to ensuring patients have the opportunity to receive the safest and most effective treatments for mental health which include psychedelic-assisted therapies.

Australia has an incredible opportunity to lead the world in this promising new field and I'm pleased to be supporting Emyria and the clinicians of the Pax Centre develop leading programs for their patients." said Dr. Sessa.



Dr. Sessa's extensive experience and deep expertise in psychedelic research and integrative psychotherapy make him ideally suited to support Emyria's broadening psychedelic-assisted therapy programs across MDMA, psilocybin and ketamine. As one of the UK's foremost figures in psychedelic research and clinical medicine, he brings to the team 25 years of experience in psychiatry, including extensive work with ketamine-assisted therapy in community clinics and clinical research settings.

Emyria's recent acquisition of the Pax Centre means the Company has the multi-disciplinary staff, fit-for-purpose facilities and a suitable patient population necessary to integrate KAT alongside its MDMA-assisted therapy program and evolving psilocybin-assisted therapy initiatives and underscores Emyria's commitment to leading the development and delivery of innovative and sustainable mental health solutions where the early evidence shows promise.

Dr. Sessa will also support Emyria with quality assurance and overall program evaluation efforts related to its broader psychedelic-assisted therapy programs to ensure the maintenance of high-quality standards, but without directly managing patient care.

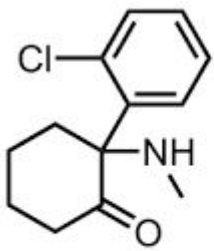
The next step in preparation in the next 2-3 months is for Emyria to work with Dr. Sessa to refine a set of unique KAT protocols for the Pax Centre also covering therapeutic models to be used, develop the supporting standard operating protocols and train clinicians in administration and monitoring of ketamine.

Ketamine in mental health:

Emerging research is spotlighting the potential of ketamine as a groundbreaking treatment for severe and treatment-resistant depression. In Australia's largest-of-its-kind trial of generic ketamine, 20% of participants achieved total remission from their symptoms after a month of bi-weekly injections, and nearly a third experienced a 50% reduction in symptom severity. However, these benefits began to recede after discontinuing the treatment, emphasising the possible requirement for prolonged or sustained treatment to maintain its antidepressant effects.¹

Additionally, recent trials highlight the synergistic relationship between generic ketamine and psychological therapy and evidence suggests that combining ketamine with certain psychological therapies can bolster its efficacy and durability. For instance, pairing ketamine with motivational enhancement therapy might enhance the drive to abstain from substances like recreational drugs and alcohol.²

Dr. Michael Winlo, CEO at Emyria, commented, **"With our launch of ketamine-assisted therapy at the Pax Centre, and the invaluable expertise of Dr. Ben Sessa, Emyria is demonstrating its commitment to lead in the delivery and development of promising emerging mental health treatments. The KAT offering will sit alongside our MDMA and psilocybin-assisted therapy programs and we believe the robust data we will gather with every patient will allow us to refine and enhance these protocols to help set new standards in care."**



ketamine

COMMERCIAL READINESS & POTENTIAL OF KETAMINE-ASSISTED THERAPY

Johnson & Johnson's proprietary ketamine nasal spray for depression - Spravato™ (esketamine) - recently reported global sales of US\$169M in Q2, 2023 alone, a nearly 100% increase year-on-year.³ In Australia, over 8 million antidepressant prescriptions were dispensed in the March quarter alone.⁴ These data suggest there is a strong and growing demand for rapid-acting antidepressants.

Emyria has identified a distinct opportunity to provide scalable ketamine-assisted therapy (KAT) within its multidisciplinary service which is already prepared to deliver MDMA-assisted therapy for PTSD with psilocybin-assisted therapy for treatment resistant depression in development. Emyria has over 20 clinicians trained and expects to quickly launch a unique and scalable KAT program to deliver timely and innovative care to those awaiting effective treatment.

Under the expert guidance of Dr. Ben Sessa, and with Emyria's commitment to collecting meaningful clinical data from each patient undergoing KAT, the Company expects to develop unique protocols that can deliver great patient outcomes and that can also be licenced to other partners to meet demand.

Protocol development is underway and the Company expects its first patients expected at the end of Q3, 2023.

REFERENCES:

- [1] Loo, C., et al (2023). Efficacy and safety of a 4-week course of repeated subcutaneous ketamine injections for treatment-resistant depression (KADS study): Randomised double-blind active-controlled trial. The British Journal of Psychiatry, 1-9. doi:10.1192/bjp.2023.79
- [2] Grabski M, et al Adjunctive Ketamine With Relapse Prevention-Based Psychological Therapy in the Treatment of Alcohol Use Disorder. Am J Psychiatry. 2022 Feb;179(2):152-162. doi: 10.1176/appi.ajp.2021.21030277. Epub 2022 Jan 11. PMID: 35012326.
- [3] Johnson & Johnson Q2 Results, <https://www.jnj.com/johnson-johnson-reports-q2-2023-results>
- [4] <https://www.aihw.gov.au/mental-health/monitoring/mental-health-services-activity-monitoring>

The Advantages Of Emyria's Integrated Service For The Delivery Of Psychedelic Therapies:

1. **Safety and Professional Expertise:** Given the potent and often unpredictable nature of psychedelic substances, it's essential to administer them in a controlled, professional environment. Patients can experience intense psychological shifts during these therapies, requiring expert oversight and immediate response capabilities to manage any adverse reactions. An integrated clinical service ensures that this safety and expertise is consistently maintained.
2. **Continuity of Care:** Psychedelic-assisted therapy isn't a one-off treatment; it's a journey that requires pre-session preparation, the session itself, and post-session integration work. Delivering this therapy within a multidisciplinary service facilitates a seamless continuity of care, ensuring that all stages of the treatment are harmoniously interconnected.
3. **Comprehensive Understanding:** In an integrated clinical service, all aspects of a patient's health - physical, psychological, and social - are considered. This comprehensive view is crucial for the success of psychedelic-assisted therapy, as it allows for a deeper understanding of the patient's condition and tailoring the therapeutic process accordingly.
4. **Psychotherapeutic Support:** Psychedelic experiences often unveil deeply embedded psychological content that can be difficult for patients to process. An integrated service with mental health professionals such as psychiatrists, psychotherapists, and social workers can provide essential support during and after these intense experiences, enhancing the therapy's efficacy.

OUR DELIVERY ADVANTAGE | DATA DRIVEN, MULTIDISCIPLINARY CARE

SERVICE MODEL	KEY STRENGTHS	KEY LIMITATIONS	EMYRIA ADVANTAGES
GP Clinics	Accessible, generalised care	Limited support; not specialised	✓ Our model provides specialised care with <u>robust support</u>
Specialists	High-level, specialised care	Often do not address physical health	✓ Our model offers multidisciplinary care covering <u>mental</u> & <u>physical</u> health
"Single service" clinics (eg. "Ketamine Clinics")	Specialised service	Referral risk for clinicians. "Where do my patients go if treatment fails?"	✓ Our model offers a <u>suite of services</u> before, during & after care
Academic & Research Centers	Cutting-edge research and treatments	Not focused on scalable, cost effective delivery	✓ Our model combines innovative approaches with <u>scalability</u> and <u>cost effective delivery</u>
EMYRIA MODEL	Multidisciplinary, data-driven, scalable	---	✓ Outperforms other models by delivering comprehensive, data-driven care at scale; + next-generation therapy development

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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	✓
Develop psilocybin therapy model	
Expansion of treatment offerings	
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)	

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.

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 The Pax Centre | 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



ABOUT Emerald Clinics | emeraldclinics.com.au

Emerald Clinics is an Australian-based, patient-centric clinical services 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.