

Emyria Secures Ethics Endorsement for Psilocybin-Assisted Therapy Program

HIGHLIGHTS

Emyria's lead psychiatrists have received endorsement from the ACT Health Ethics Committee for its psilocybin-assisted therapy program.

The approval is the first stage of a 2-step evaluation; final approval is still required from Australia's Therapeutic Goods Administration and is expected within the next month.

Recent findings suggest that psilocybin-assisted therapy, with psychological support, leads to long-term improvements in depressive symptoms for treatment-resistant depression.¹

The psilocybin program complements Emyria's existing MDMA-assisted therapy programs, reinforcing Emyria's leadership in medication-assisted therapy delivery and development for serious mental health conditions.

Emyria Limited (ASX: EMD) ('Emyria', or the 'Company') is pleased to announce its lead psychiatrists have received endorsement from the ACT Health Ethics Committee, supporting the submission of Authorised Prescriber applications with the TGA for its psilocybin-assisted therapy program targeting treatment-resistant depression.

This endorsement is an important step towards expanding Emyria's capacity to offer innovative mental health treatments directly to eligible patients under TGA's Authorised Prescriber framework. With TGA approval anticipated in the next month, Emyria will be amongst a select group capable of offering both MDMA- and psilocybin-assisted therapies, to eligible patients, backed by its experience in safe, evidence-based mental health care.

Emyria's founding mission is to maximise patient outcomes by delivering safe and effective therapies, while continuously gathering data to refine and improve our treatment protocols. By expanding into psilocybin-assisted therapy, Emyria aims to not only address critical gaps in care for those with treatment-resistant depression but also to enhance the understanding and effectiveness of innovative mental health treatments. This data-driven approach strengthens Emyria's commitment to pioneering new options for complex mental health challenges while building a foundation to develop future treatments.

Emyria's Leadership in New Treatment Delivery and Development

Following the TGA's rescheduling of MDMA and psilocybin for PTSD and treatment-resistant depression², access to these therapies remains limited to clinical trials or specialist psychiatrists who have secured Authorised Prescriber (AP) status. Achieving AP status requires endorsement from an NHMRC-accredited ethics committee or the Royal Australian and New Zealand College of Psychiatrists (RANZCP) and involves submitting a comprehensive care model that includes psychotherapy and patient monitoring.

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Emyria to Expand Treatment Programs

For over a year, Emyria has led the evaluation of a real-world MDMA-assisted therapy program for PTSD ³ from a purpose-built facility ⁴ and with specially trained clinicians. Adding psilocybin-assisted therapy to this framework demonstrates Emyria's unique leadership and opportunity to deliver, and advance, new options for major unmet needs in mental health.

Recent Research on Psilocybin Therapy for Treatment-Resistant Depression

About a third of patients with depression experience treatment-resistant depression), meaning they do not respond to conventional therapies.⁵ This significant group of treatment-resistant patients highlights the urgent need for alternative treatment options. Recent findings published in *The Lancet* highlight psilocybin's potential to provide substantial, long-lasting improvements in depressive symptoms and quality of life for individuals with moderate-to-severe depression, even after other treatments have failed ¹. This research supports Emyria's expansion into psilocybin-assisted therapy, building on our experience with MDMA-assisted therapy and reinforcing our commitment to providing effective options for complex mental health conditions.

Emyria's Managing Director, Dr. Michael Winlo, commented: *"This ethics endorsement is a significant milestone in our commitment to delivering effective, evidence-based treatments for patients with complex mental health needs. By expanding into psilocybin-assisted therapy alongside our established MDMA program, Emyria is broadening care options for patients while advancing our mission to continuously improve these treatments and patient outcomes over the long-term. Emyria is uniquely positioned to lead in this space, and we're excited to build on our experience to dramatically improve health outcomes safely and responsibly."*

References:

1. DE, Tommaso Barba, et al Effect of psilocybin versus escitalopram on depression symptom severity in patients with moderate-to-severe major depressive disorder: observational 6-month follow-up of a phase 2, double-blind, randomised, controlled trial, *eClinicalMedicine*, Volume 76, 2024, 102799, <https://doi.org/10.1016/j.eclinm.2024.102799>.
2. <https://www.tga.gov.au/products/unapproved-therapeutic-goods/mdma-and-psilocybin-hub>
3. See ASX release 02 September 2024
4. See ASX release 09 April 2024

This release has been approved by the Board of Emyria.

For further information, investment opportunities, or more about our approach to mental health treatment, please contact:

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Emyria Limited develops and delivers new treatments for mental health and select neurological conditions through through an integrated model of direct clinical services and drug development:

generates

Emyria Healthcare: Evidence-based treatment for patients not finding relief from conventional care while also helping evaluate emerging new therapies like MDMA-assisted therapy for PTSD

informs

Emyria Data: Robust and ethically-sourced Real-World Data gathered with patients and used to improve Emyria's unique therapy and drug development programs.

Emyria's Pipeline: New psychedelic-assisted therapies and drug treatments for mental health and select neurological diseases.

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Risks associated with the use of Psilocybin and MDMA

All medicines carry risks and specialist prescribers, such as registered psychiatrists, are best placed to assess the suitability of a new medication against a patient's individual circumstances and medical history before proceeding. Adverse effects of psilocybin can include temporary increase in blood pressure and a raised heart rate. Adverse effects of MDMA include high blood pressure, increased pulse rate, faintness, and panic attacks, and in some rare cases it can cause loss of consciousness or trigger seizures. Other side effects include involuntary jaw clenching, decreased appetite, restless legs, nausea, headache, sweating and muscle/joint stiffness. These effects of psilocybin and MDMA are unlikely at low doses in the treatment regimens used in psychedelic-assisted psychotherapy while appropriately managed in a controlled environment with direct medical supervision.