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Emyria Presents to U.S FDA At Psychedelics Medicine Hearing

Executive Chairman outlines Emyria's Australian treatment-delivery experience directly to U.S. regulators

- **Emyria Limited (ASX: EMD) has presented in person to the U.S. Food and Drug Administration (FDA)** at its public hearing, examining considerations for the potential future therapeutic use of psychedelic drugs[1,2].
- **Executive Chairman Greg Hutchinson represented Emyria at the FDA's White Oak Campus in Maryland,** presenting insights from the Company's experience delivering treatments within Australia's regulated clinical framework.
- **Emyria's operating capabilities directly align with key implementation areas examined by the FDA,** including provider training and credentialing, patient safety, access, clinical data collection and standardisation.
- **Emyria brings differentiated real-world experience, treating patients in regulated clinical settings**, spanning psychiatrist-led governance, therapist training, treatment delivery, specialist infrastructure and evidence generation.
- **FDA participation increases the Company's visibility among regulators, drug developers, healthcare providers and other stakeholders** as it evaluates clinical, research and commercial opportunities in the world's largest healthcare market.

Emyria Limited (ASX: EMD) ("Emyria", or the "Company") a leader in innovative mental health treatments, is pleased to announce Executive Chairman Greg Hutchinson delivered in-person remarks to the U.S. Food and Drug Administration (FDA) at its public hearing, "Considerations for Potential Future Therapeutic Use of Psychedelic Drugs," held on 14 September 2026 at the FDA's White Oak Campus in Silver Spring, Maryland[1,2].

Mr Hutchinson presented insights from Emyria's experience delivering treatments within Australia's regulated clinical framework, providing U.S. regulators and other stakeholders with a practical perspective on the systems required to support safe and consistent treatment delivery in supervised healthcare settings.

Emyria was selected by the FDA for a limited in-person speaking position at the hearing, which brought together regulators, federal healthcare representatives, drug developers, healthcare providers and other stakeholders to consider practical issues associated with the potential future therapeutic use of psychedelic medicines.

Real-World Treatment Experience

The FDA hearing examined four key areas relevant to the potential future implementation of psychedelic-assisted therapies:

- Provider training and credentialing;
- Patient safety;
- Access;
- Clinical data collection and standardisation.

Emyria's Australian clinical operations already span each of these areas

The Company has developed capabilities across the treatment pathway, including:

- Psychiatrist-led clinical governance and authorised prescribing;
- Therapist recruitment, training and credentialing;
- Patient screening, preparation, dosing and follow-up;
- Specialist treatment facilities and clinical infrastructure; and
- Systematic collection of clinical outcomes and real-world evidence.

While much of the global psychedelic medicines sector remains focused on drug development, Emyria has built practical capability around the clinical infrastructure and treatment-delivery systems that may ultimately be required to translate psychedelic medicines into broader regulated healthcare use.

The United States is the world's largest healthcare market by expenditure, with approximately **US$5.3 trillion** in healthcare spending in 2024[3].

Presenting directly to the FDA represents an important step for Emyria, providing greater visibility among stakeholders involved in the development, regulation and potential future delivery of psychedelic medicines.

Emyria is assessing opportunities to apply its Australian clinical capabilities, reimbursed treatment-delivery experience and evidence-generation platform in the United States through clinical partnerships, treatment-delivery collaborations, research programs and real-world evidence initiatives.

Executive Chair, Greg Hutchinson, commented:

"Presenting directly to the FDA was important validation that what Emyria and Australia has, remains uncommon globally. Real-world experience treating real-world patients within a regulated healthcare system.

As psychedelic medicines move toward broader adoption, the challenge is no longer just about drug development, it is about building the systems to deliver treatment safely, consistently and at scale. We believe Emyria's expertise can create significant opportunities as we consider how we can support the United States."

References

1. https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/considerations-potential-future-therapeutic-use-psychedelic-drugs-public-hearing-09142026
2. See ASX announcement 10 September 2026
3. https://www.healthaffairs.org/doi/10.1377/hlthaff.2025.01683
4. https://www.youtube.com/live/5Kg1gj3KbAI

This announcement has been approved by the Executive Chair.

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

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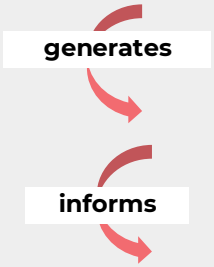
Emyria Limited develops and delivers new treatments for mental health and select neurological conditions through an integrated model of direct clinical services and treatment development:



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

Emyria Data: Robust and ethically sourced Real-World Data gathered with patients 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.

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.

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.

Risks associated with the use of MDMA, MDMA-inspired compounds and psilocybin

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 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. Adverse effects of psilocybin can include temporary increase in blood pressure and a raised heart rate. There may be some risk of psychosis in predisposed individuals. The effects of MDMA and psilocybin 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. The risk profile of the MDMA inspired compounds is currently unknown.

The availability of these products is subject to the safety and efficacy of the products being tested through clinical trials. Emyria makes no representations or warranties as to the safety or efficacy of the products or the products' ability (or the ability of its key compounds) to be used in the treatment of indications such as PTSD. There are currently no approved products containing MDMA, psilocybin or MDMA inspired compounds that the TGA has evaluated for quality, safety and efficacy.