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U.S. FDA SELECTS EMYRIA TO PRESENT AT PSYCHEDELIC MEDICINES HEARING

EMD secures limited in-person speaking position at FDA's U.S. psychedelic medicines hearing

- **Emyria Limited (ASX: EMD) has been selected by the United States Food and Drug Administration (FDA) to deliver in-person remarks** at a public hearing on the future therapeutic use of psychedelic drugs, to be held at the FDA's White Oak Campus in Maryland on 14 September 2026.
- **FDA selection places Emyria directly in a U.S. federal discussion on the future delivery of psychedelic medicines,** spanning provider training and credentialing, patient safety, access, and clinical data collection and standardisation.
- **Emyria brings real-world experience treating patients with psychedelic-assisted therapies in regulated Australian clinics**, supported by psychiatrist-led clinical governance, trained therapists, specialist infrastructure, payer-supported access and real-world data collection — providing practical experience across the same implementation areas now being examined by the FDA.
- **FDA selection provides Emyria with a unique opportunity to bring its real-world treatment experience directly in front of U.S. regulators** as the Company evaluates opportunities within the world's largest healthcare market.

Emyria Limited (ASX: EMD) ("Emyria", or the "Company") a leader in innovative mental health treatments, has been **selected by the U.S. Food and Drug Administration to deliver in-person remarks** at the FDA's upcoming public hearing[1] *"Considerations for Potential Future Therapeutic Use of Psychedelic Drugs."*

The hearing will be held on **14 September 2026 at the FDA's White Oak Campus** in Silver Spring, Maryland and runs from 12:30 to 4:30 pm ET.

The FDA is convening the hearing to obtain perspectives on the potential future therapeutic use of psychedelic drug products in supervised and supportive settings, including practical considerations relevant to safe, effective and scalable treatment delivery.

SELECTED FOR LIMITED IN-PERSON SPEAKING POSITION

Emyria has been formally advised by the FDA that it has been selected as one of a limited number of in-person speaking position at the hearing.

The selection gives Emyria an opportunity to contribute **real-world Australian treatment-delivery experience to a U.S. federal discussion** examining the potential future delivery of psychedelic medicines targeting an audience which comprises regulatory authorities, drug sponsors, providers and other relevant stakeholders.

FDA HEARING TOPICS ALIGN WITH EMYRIA'S OPERATING PLATFORM

The FDA has identified four principal areas for discussion:

- Provider training and credentialing;
- Promotion of patient safety;
- Considerations for access; and
- Best practices for data collection and standardisation.

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

Through Australia's regulated psychedelic-assisted therapy framework, Emyria has built direct operating experience across the clinical, workforce, infrastructure, access and data requirements now central to the FDA discussion.

EMYRIA'S REAL-WORLD EXPERIENCE TREATING PATIENTS IN REGULATED CLINICS

Australia permits authorised psychiatrists to prescribe MDMA for post-traumatic stress disorder (PTSD) and psilocybin for treatment-resistant depression (TRD) within regulated clinical settings[2].

Emyria has leveraged this framework to build 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;
- Systematic collection of clinical outcomes and real-world evidence.

Together, these capabilities give Emyria real-world operating experience and practical insight into the clinical, workforce, infrastructure, access and data requirements likely to underpin broader psychedelic-assisted therapy delivery.

POSITIONING EMYRIA IN THE WORLD'S LARGEST HEALTHCARE MARKET

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

Emyria is actively assessing opportunities to deploy 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.

Selection to address the FDA hearing provides Emyria with a unique opportunity to demonstrate its operating experience directly to U.S. regulators as well as Industry and other

providers as the Company evaluates opportunities to apply its capabilities across the world's largest healthcare market.

Executive Chair, Greg Hutchinson, commented:
"Being selected to address the FDA hearing gives Emyria a rare opportunity to bring real-world experience from Australia directly in front of U.S. regulators. We have operated under Australia's regulated framework since 2023, giving us practical experience across the same areas the FDA is now examining — provider training, patient safety, access and real-world data.

"The United States is the world's largest healthcare market, and this hearing puts Emyria directly into an important federal discussion about how psychedelic medicines may ultimately be delivered. It provides a unique platform to demonstrate what we have already built in Australia as we pursue opportunities to apply that experience in 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. https://www.tga.gov.au/news/media-releases/change-classification-psilocybin-and-mdma-enable-prescribing-authorised-psychiatrists
3. https://www.healthaffairs.org/doi/10.1377/hlthaff.2025.01683

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:

generates

informs

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.