ASX Announcement

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Emyria welcomes TGA-commissioned Independent Expert Report on MDMA and Psilocybin

Key points:

- Emyria welcomes the Independent Expert Panel report (released 30 Sep '21) on the therapeutic value, benefits and risks of methylenedioxymethamphetamine (MDMA) and psilocybin for the treatment of mental, behavioural or developmental disorders, concluding:

  > *"...that MDMA and psilocybin may show promise in highly selected populations but only where these medicines are administered in closely clinically supervised settings and with intensive professional support." [1]*

- The report remarked that both treatments were well tolerated in supervised trials and that statistically significant differences for both MDMA and psilocybin were observed between both inactive and active treatments

- The Expert Panel was formed by the Therapeutic Goods Administration (TGA) Scheduling Delegate (decision maker) to assist with a determination on whether to down-schedule MDMA and psilocybin from Schedule 9 (prohibited drugs) to Schedule 8 (controlled drugs)

- The Panel's full report will now be considered by the Advisory Committee of Medicines Scheduling (ACMS) at the 3 November 2021 meeting with the TGA's final decision anticipated to be published the first week of December 2021

- Emyria is currently developing a scalable, evidence-based clinical delivery model for MDMA-assisted therapy, in a non-exclusive partnership with Mind Medicine Australia, who led the initial rescheduling application with the TGA

- Emyria's **EMDMA-001 phase IIb protocol** ensures that patients are treated in a *"closely supervised setting"* and provided *"intensive professional support"*, which follows the guidance from the Expert Panel Report

Emyria Limited (ASX: EMD) (Emyria or the Company), a data-backed care delivery company focussed on accelerating drug development and improving patient care, welcomes the Independent Expert Panel report [1] evaluating the therapeutic value, benefits and risks of methylenedioxymethamphetamine (MDMA) and psilocybin for the treatment of mental health conditions.

The Independent Expert Panel was established by the Therapeutic Goods Administration (TGA) to assist the Advisory Committee of Medicines Scheduling (ACMS) in their upcoming deliberations on whether to support the rescheduling of MDMA and psilocybin from Schedule 9 to Schedule 8.

This current rescheduling consideration for MDMA and psilocybin follows the 2016 rescheduling of medicinal cannabis from Schedule 9 to Schedule 8.

Emyria's Managing Director, Dr Michael Winlo, said: *"The Independent Expert Panel has reviewed high quality published research into MDMA and psilocybin and concluded that, with appropriate clinical oversight and psychological support, these treatments are reliably safe and effective for certain patients.*

We are encouraged by the approach of the report, and its conclusions, and believe it will encourage further research and investment into these treatments to help develop evidence-based ways they can be scalably and safely administered to patients.

With Emyria's expert partners, national clinical network and data infrastructure, we believe there is a growing opportunity for Emyria to help lead in the development of MDMA-, psilocybin-, and other psychedelic-assisted therapies for patients with major mental health concerns."

EMDMA-001

Pending successful ethics approval, Emyria's first psychedelic-assisted program **EMDMA-001** will leverage Emyria's existing clinical and data infrastructure, and trained therapists, to assess the safety, efficacy and cost-effectiveness of MDMA-assisted psychotherapy in treating patients with Post Traumatic Stress Disorder (PTSD).

With the support of Emyria's broader clinical and partner ecosystem, Emyria then plans to develop additional psychedelic-assisted therapy protocols, novel treatments and programs to further the development, improvement and access of these treatments.

While MDMA and psilocybin remain Schedule 9 drugs Emyria's programs can progress as ethics-approved clinical trials. Rescheduling MDMA and psilocybin to Schedule 8 would create a pathway for these treatments to become registered and reimbursed medicines following the requisite pivotal clinical trials and health economics analysis and could therefore improve patient access.

The Independent Expert Panel Report

The report was informed by a meta-analysis of eight studies on MDMA and six on psilocybin. Studies were included for meta-analysis if they met thresholds for size of effect observed, quality of evidence provided and the applicability of the evidence to real-world use in Australia, currently and into the future. Meta-analyses can help to establish the relative efficacy of interventions where large studies may be impractical.

The report concluded that both treatments were well tolerated in supervised trials and that statistically significant differences for both MDMA and psilocybin were observed between both inactive and active treatments. The report also stressed that these outcomes were achieved in highly supportive and structured environments, including intense psychotherapy sessions in many cases, indicating that the clinical delivery component, as well as the drug treatment, is an important consideration of successful treatment delivery.

This announcement has been approved and authorised for release by the Managing Director of Emyria Limited.

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References:
[1] https://www.tga.gov.au/independent-expert-panel-mdma-and-psilocybin

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About Emyria (www.emyria.com)

Emyria Limited is a data-backed clinical drug development and care delivery company.

Emyria's Treatments target large unmet needs and are focused on obtaining approval ("registration") with major global regulators. Emyria's treatment development programs are informed by insights generated from extensive analysis of **Emyria Data** - deep, ethically-sourced clinical evidence that is gathered with patients across Emyria's independent clinical services (**Emerald Clinics** - www.emeraldclinics.com.au)

Emyria Data provides deep treatment insights and is therefore a source of unique IP, strategically designed drug development and personalised care programs.

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.