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Emyria partners with **Mind Medicine Australia** to develop national care program and data registry for psychedelic-assisted therapies

Highlights:

- **Emyria and Mind Medicine Australia to develop an evidenced based, best practice, model to support the safe and appropriate initiation, delivery and monitoring of psychedelic-assisted therapies in Australia**
- **Partnership will also develop a national clinical evidence registry to support research into the safety, effectiveness and cost benefits of psychedelic-assisted therapy enabled by Emyria's Real-World Evidence (RWE) data platform**
- **Initial focus will be specialist-directed use of MDMA assisted therapies for treatment resistant post-traumatic stress disorder and psilocybin assisted therapies for treatment resistant depression**
- **Partnership to leverage Emyria's experience with unregistered medicines for patients with unmet needs across its national network of clinics – Emerald Clinics**

Emyria Limited (ASX: EMD) (Emyria or the Company), a company that accelerates treatment development for patients with unmet needs, is pleased to announce a partnership with Mind Medicine Australia to co-develop a gold-standard and data-driven clinical model for the safe provision of psychedelic-assisted therapies in Australia.

Emyria's Managing Director, Dr Michael Winlo, said: "*We're delighted to support Mind Medicine Australia by developing a scalable psychedelic-assisted therapy care model for patients suffering from treatment resistant post-traumatic stress disorder, treatment resistant depression and substance abuse. Emyria has unique expertise caring for patients with unmet needs while also generating high quality clinical evidence using our RWE data platform. This partnership has the potential to expand the therapeutic options available for our patients with unmet needs while also creating a unique data registry that can accelerate treatment development and registration.*"

Under the terms of the partnership, Emyria will design a care model describing how psychedelic-assisted therapies could be delivered safely to patients with major mental health concerns, pending the successful rescheduling of psilocybin and MDMA by the TGA (please see **TGA note** below). Mind Medicine Australia will provide access to its international network of experts, clinical trainers and treatment model strategies. The model will start with psilocybin and MDMA-assisted therapies and draw on pivotal research conducted recently in North America and Europe.

Emyria will also apply its remote monitoring technology and lead the construction of a longitudinal data registry. The registry will collect real world clinical data on diagnoses, concomitant medications, dosing information and patient responses to psychedelic-assisted treatments as measured using validated clinical and patient-reported endpoints. The data will support ongoing research into the safety, effectiveness and cost benefits of psychedelic-assisted therapies for major mental health concerns compared to current alternatives.

Mind Medicine Australia's Chairman, Peter Hunt AM, said, "*Mental health is a growing global health concern and new care models are needed. Psychedelic-assisted therapies show incredible promise, but further high-quality clinical evidence is needed to demonstrate their effectiveness. This is why we're excited to work with Emyria, who can help us develop a model of care that provides patients safe access to these promising treatments. The partnership will also allow us to generate high-quality data, which can inform ongoing research and development efforts and guide evidence-based access to these therapies for patients in need, where appropriate.*"

Both parties will contribute in-kind to the partnership. Commercial opportunities that may arise from the development of these therapies will be negotiated on a case-by-case basis.

TGA Note:

Under Australia's Therapeutic Goods Administration (TGA), psychedelic medications such as psilocybin and MDMA are currently Schedule 9 of the Uniform Scheduling of Medicines and Poisons (which deals with Prohibited Substances). Despite approvals being given by the TGA under the Special Access Scheme current State Government legislative restrictions in most States of Australia mean that they are only available via approved clinical research trials which include oversight by an institutional research ethics committee and careful monitoring and reporting of efficacy and safety outcomes.

There is an active rescheduling proposal before the TGA so that they can be more easily used as clinical therapies in medically controlled environments for the treatment of key mental illnesses. The rescheduling would move these medicines to Schedule 8 (which deals with Controlled Medicines), the same category as THC-containing cannabinoid medicines. For more information : https://www.tga.gov.au/consultation-invitation/consultation-proposed-amendments-poisons-standard-acms-accs-and-joint-acmsaccs-meetings-november-2020.

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

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About Emyria (www.emyria.com)
Emyria Limited creates clinical evidence that accelerates the development of new treatments and care models for patients with unmet needs. Emyria achieves this by analysing the high quality clinical data gathered from its specialist clinical network – Emerald Clinics (www.emeraldclinics.com.au) – and turning that into Real-World Evidence (RWE). Emyria's data supports the development and registration of new and promising treatments for patients with unmet medical needs by providing unique, real-world insights into the safety, quality and efficacy of those unapproved treatments, in real patients in the community. Emyria's data assets are also a source of unique IP for Emyria, which along with its remote patient monitoring technologies, data platforms and care models, further improve the quality of its RWE data assets and insights as well as the care provided to patients.

About Mind Medicine Australia (https://mindmedicineaustralia.org)
Mind Medicine Australia ("MMA") is a registered charity that was set up to help alleviate the suffering caused by mental illness in Australia through expanding the treatment options available to medical practitioners and their patients. MMA is focused on developing the ecosystem in Australia to enable psychedelic-assisted therapies to be available through the medical system as safe and effective treatments for a range of mental illnesses. The organisation operates as a nexus between medical practitioners, academia, government, regulatory bodies, philanthropists, and other partners.

MMA is particularly focused on the clinical application of medicinal psilocybin and medicinal MDMA as part of therapy for key mental illnesses such as Depression, Post Traumatic Stress Disorder and Substance Abuse. MMA's strategy focuses on awareness building amongst all key stakeholder groups such as medical practitioners, regulators, researchers, patients and carers; the training of therapists in these modalities; the development of a Centre of Excellence in Emerging Mental Health Therapies; and all the logistics involved in developing the right ethical and legal framework, the manufacturing of these medicines and the rollout of specialist clinics.

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.