

## Emyria and Mind Medicine Australia to launch psychedelic-assisted therapy program (EMDMA-001) for PTSD

### Highlights:

- Emyria and Mind Medicine Australia announce their **first psychedelic-assisted therapy care program** (EMDMA-001) for sufferers of treatment resistant **post traumatic stress disorder** (PTSD)
- **EMDMA-001** has been modelled on a major Phase III clinical trial developed by the Multidisciplinary Association for Psychedelic Studies (MAPS)
- Pending successful ethics review and the finalisation of all logistics,, EMDMA-001 will commence with a Phase II, open-label clinical trial of MDMA-assisted psychotherapy at Emyria's **fit-for-purpose clinic in Melbourne** before expanding to other sites
- **EMDMA-001** will utilise specially-trained psychotherapists graduating from Mind Medicine Australia's first **Certificate in Psychedelic-Assisted Therapy** (CPAT) training program end of this month
- **EMDMA-001** will leverage **Emyria's established clinical infrastructure** and **data capture technology** to provide safe patient access while also generating **high quality, Real-World Evidence** to inform future development
- It is expected that this first program will be an important first step towards delivering safe, accredited, cost-effective, scalable and **evidence-based, psychedelic-assisted therapy services across Australia**

**Emyria Limited (ASX: EMD)** (Emyria or the Company), an innovative drug development and clinical services company, is pleased to announce the launch of EMDMA-001, a psychedelic-assisted therapy program targeting Posttraumatic Stress Disorder (PTSD) developed with partner Mind Medicine Australia. *[Ann 19 Nov 20]*

As a first step, and pending ethics approval, Emyria will Sponsor a major, independently monitored, clinical trial targeting treatment resistant PTSD with evidence-based MDMA-assisted therapy .

A key priority of this first program is to help evaluate the long-term safety, efficacy and cost benefits of MDMA-assisted psychotherapy. Such **evidence is needed**, along with **fit-for-purpose clinical infrastructure and trained therapists** in order to deliver psychedelic-assisted care in a safe, standardised and scalable way.

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**Emyria's Managing Director, Dr. Michael Winlo says:** "There is growing international interest in the promise of psychedelic-assisted therapies for treating our most challenging mental health conditions. However, the care model and the drug intervention are intrinsically linked. This means any treatment will require a **properly prepared and equipped clinical service** - including **specially trained clinicians and therapists**. We also require more **robust clinical evidence** to guide future innovation and development in this space.

At Emyria, our strength is in providing safe access to unregistered treatments while also generating clinical evidence. To date, we have cared for over 4,000 patients with major unmet needs (including more than 80 patients suffering with treatment resistant PTSD) and collected high-quality Real-World Evidence.

Emyria's clinical advisory, site network and data infrastructure is uniquely positioned to support safe and scalable psychedelic-assisted therapy, much like we have demonstrated and accomplished with cannabinoid medicines.

Our goal is to build a unique clinical database that we hope can help **optimise the development of existing and novel treatments** while also allowing Emyria and our partner, Mind Medicine Australia to become the **trusted and accredited clinical service of choice.**"

**Mind Medicine Australia's Chairman, Peter Hunt AM says:** "We are delighted to be working with Emyria on developing the pathway for the use of evidence-based psychedelic assisted therapies for the treatment of key mental illnesses in Australia.

Post traumatic stress disorder is a debilitating condition and existing modalities (primarily pharmaceutical medicines and psychotherapy) can have relatively low remission outcomes and – in the case of the pharmaceuticals – can have nasty side effects.

MDMA assisted psychotherapy is showing very high remission rates in overseas trials and has also been shown to have high levels of safety and to be non-addictive when used in medically controlled environments. Negative side effects have also been minimal. Therapists have been specifically trained for this work through our certificate course and appropriate protocols developed with Emyria.

The trial approach being taken by Emyria is also consistent with the Federal Government's recently announced grant of \$15 million for trials utilising hallucinogens or stimulant drugs supported by psychotherapy for treatment resistant mental illnesses."



Mind medicine Australia ([www.mindmedicineaustralia.org](http://www.mindmedicineaustralia.org)) is an Australian registered charity that seeks to alleviate the suffering caused by mental illness in Australia through expanding the treatment options. The organisation is focused on the development of safe and effective psychedelic-assisted therapies to cure a range of mental illnesses.

### **Mental health is a growing health concern**

Mental health currently tops the list of chronic health conditions in Australia with 4.8 million people, or 20.1% of all Australians affected. [1]

### **Veteran's are particularly affected by PTSD**

Mental health is a particular concern of veterans as evidenced by the recent launch of a Royal Commission into Defence and Veteran Suicide by Prime Minister Scott Morrison. [2] While, between five and ten percent of the general community are likely to develop PTSD at some point in their lives, rates amongst veterans are estimated close to 20 percent. [3]

### **Psychedelic-assisted therapy offers potential**

The past Chair of the Australian Defence Force (1998-2002), Admiral Chris Barrie, recently encouraged the Australian Government to consider the clinical use of specific psychedelics to help veterans recovering from trauma. [4]

In fact, there is now a strong and emerging body of international evidence that shows that substances such as ketamine, psilocybin, and 3,4-methylenedioxymethamphetamine (MDMA), when used in a controlled environment and supported by psychotherapy, offer a promising new approach to effectively treating pernicious mental illnesses that are resistant to first-line treatments. [5]

The Multidisciplinary Association for Psychedelic Studies (MAPS) recently announced results of a Phase 3 trial of MDMA-assisted therapy for PTSD and reported a significant reduction in PTSD symptoms compared to those who received placebo with therapy ( $p < 0.0001$ ). 67% of the group who received MDMA, compared to 32% of the group who received placebo, no longer qualified for a PTSD diagnosis after three treatment sessions. [6]

Psilocybin-assisted therapy for treatment resistant depression and major depressive disorder and MDMA-assisted therapy for PTSD have been granted 'Breakthrough Therapy' status by the US Food and Drug Administration (FDA). [7]

**Beyond EMDMA-001**, Emyria plans to further explore other MDMA- and psilocybin-assisted therapy programs in treating disorders such as depression and substance abuse as mentioned in ASX release 19 November 2020.

## Australian Federal government commits \$15m to “Innovative Therapies for Mental Illness”

In recognition of the promise of this new field but also the great need for more clinical evidence, on 17 March 2021, Federal Health Minister, Greg Hunt, announced \$15m in new funding for *“Australian medical research projects that use clinical trials to assess the safety and efficacy of innovative therapies using hallucinogens and stimulant drugs supported by psychological/ psychiatric care for treatment resistant mental illness, compared to standard therapies.”* [8]

## EMDMA-001 to address major challenges in MDMA-assisted therapy

Novel research and specialised training are needed because of the way MDMA-assisted therapy is delivered. The treatment is unlike traditional psychotherapy or psychopharmacology. The psychotherapy is deeply intertwined with pharmacological intervention.

In general, MDMA-assisted therapy involves three general stages:

- **Preparation** – in which the therapist and patient get to know one another and build trust
- **Administration & Monitoring** – the patient, usually lying down and wearing an eye mask, is given a dose of MDMA and supported by two therapists during each session – which can last 6 to 8 hours
- **Integration** – the next day, and at weekly intervals for on average 3 occasions, the patient and therapist discuss the experience and how to integrate any insights into behavioural change

Some patients may need to repeat the cycles above and a clinical service must be prepared to support patients through the full experience and beyond.

Given the length of individual therapy sessions and the fact some patients may need to repeat part, or all of these cycles, there is a major need for properly prepared clinical services and specially trained psychotherapists to support psychedelic-assisted therapy at scale.

Further, any future regulation of these therapies is likely to consider the capabilities of the clinical service providing these treatments.

## TGA position on psychedelics

There is an active rescheduling proposal from Mind Medicine Australia before the TGA so that medical-grade psilocybin and MDMA can be more easily used as clinical therapies in medically controlled environments for the treatment of key mental illnesses. The rescheduling, if successful, would move these medicines to Schedule 8 (which deals with Controlled Medicines), the same category as THC-containing cannabinoid medicines.

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A final decision on rescheduling was recently delayed as the Scheduling Delegate has decided to seek further advice in relation to psilocybin and MDMA. This will include an independent expert review into the therapeutic value, risks and benefits to public health outcomes for these substances as well as seeking additional advice from the Advisory Committee on Medicines Scheduling following the review. [8]

Until rescheduling occurs, patient access to these therapies is limited to ethics-approved clinical trials (with the possible exception of Victoria which already has a permit for approvals on a case-by-case basis).

## Next steps:

The Company believes through its non-exclusive partnership with Mind Medicine Australia it is uniquely positioned to deliver the requisite clinical services while also generating robust and ethically sourced clinical evidence to advance the field.

The first cohort of trained therapists will graduate this month from Mind Medicine Australia's therapist training course and the Company has already equipped a fit-for-purpose facility. A protocol is being finalised and is expected to be submitted to ethics soon with all the necessary regulatory steps carefully observed. The company will provide further updates as the program advances.

This announcement has been approved and authorised for release by the Board of Emyria Limited. For further information:

**Dr Michael Winlo**  
**Managing Director**  
**(08) 6559 2800**  
[mwinlo@emyria.com](mailto:mwinlo@emyria.com)

**Lexi O'Halloran**  
**Media/Investor Relations**  
**+ 61 (0) 404 577 076**  
[lexi@janemorganmanagement.com.au](mailto:lexi@janemorganmanagement.com.au)

**Peter Hunt**  
**Chairman**  
**+61 (0) 419 271 483**  
[peter@mindmedicineaustralia.org](mailto:peter@mindmedicineaustralia.org)

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## About Emyria ([www.emyria.com](http://www.emyria.com))

Emyria Limited is a data-backed, drug development company. **Emyria's Treatments** target unmet needs and are focused on obtaining approval from major global regulators. Emyria's drug 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](http://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.

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## 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.

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## 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.