ASX Announcement
06 Feb 2023

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A clinical stage biotech informed by patient experience.
Tackling unmet needs in neuroscience and mental health.

Emyria to expand MDMA programs following landmark TGA decision

HIGHLIGHTS

Australia's TGA to designate MDMA and psilocybin Schedule 8 "Controlled Medicines" from July 1st 2023, facilitating access to patients via appropriately qualified Authorised Prescribers [1]

Emyria uniquely positioned to advance and help commercialise MDMA-assisted therapies via:

- **Emyria's established clinical & data infrastructure** - can support qualified Authorised Prescribers and therapists deliver MDMA-assisted therapy safely and at-scale
- **Real-World Data generation during treatment** - can inform care model innovation, drug registration programs, and advance Emyria's novel, advanced MDMA-inspired drug discovery program with partner the University of Western Australia

A short deck summarising Emyria's updated strategy accompanies this announcement

Emyria Limited (ASX: EMD) (Emyria or the Company), a clinical stage biotech that operates a clinical service, is well positioned to accelerate patient access to MDMA-assisted therapies following recent TGA regulation changes down-scheduling MDMA and psilocybin to Schedule 8 medicines from July 1st, 2023. A similar rescheduling of medicinal cannabis from Schedule 9 to Schedule 8 occurred in 2016 [2].

While the TGA was deliberating, Emyria:

- established a network of clinical partners
- developed a supply chain for Schedule 8 and 9 medicines
- identified numerous suppliers of GMP-MDMA ("patient-ready") and;
- developed a comprehensive Phase 2B clinical trial protocol for MDMA-assisted therapy. [3]

This protocol can now be adapted to support specialist psychiatrists meet the requirements for Authorised Prescriber status. This process requires an evaluation by a Human Research Ethics Committee. To date, Emerald Clinics (Emyria's clinical service subsidiary) has successfully applied for 16 Authorised Prescriber determinations relating to the provision of unregistered cannabinoid medicines to patients with unmet needs.

In addition, Emyria and the University of Western Australia **launched an MDMA-inspired drug discovery program.** The partnership has now developed, screened and filed IP for over 140 proprietary, neurologically active and novel MDMA-like compounds with the potential to become registered treatments for a range of neuropsychiatric disorders and new psychedelic treatments.

Preclinical studies are currently underway to identify candidates for next-generation MDMA-assisted therapy, and treatments for other major neurological conditions, creating a robust and unique preclinical research and development pipeline. [4]. [5].

The TGA amendments will:

- add psilocybin and MDMA to Schedule 8, permitting their use as Controlled Drugs only for treatment-resistant depression *(TRD)* and post-traumatic stress disorder *(PTSD)*, respectively
- add entries in Appendix D to restrict access to the substances under Schedule 8:
    - they can only be prescribed for the above conditions by specialist psychiatrists who have obtained approval to use the substances for treating these conditions from a human research ethics committee *(HREC)*, and then been authorised by the TGA under the Authorised Prescriber Scheme to prescribe the substances for these conditions
    - they can also be used in clinical trials into these conditions *(they are currently only accessible for clinical trials as Schedule 9 substances)*
    - the possession of the substances as Schedule 8 drugs without authority will be illegal *(for example, possession other than in accordance with a legal prescription).*

The rescheduling of MDMA opens a pathway to registration and reimbursement for MDMA and its analogues. Emyria will collaborate with clinical partners to improve patient access and ongoing research while continuing the drug discovery program in Australia and the United States to identify novel, MDMA-like compounds with the greatest therapeutic potential.

Emyria's Managing Director, Dr Michael Winlo said: ***"The mental health crisis – in Australia and around the world – continues to have untold cost, which is why the TGA's move to reschedule MDMA and psilocybin is timely and world-leading.***

Emyria is well-prepared to support the safe provision of MDMA-assisted therapies under this new change as the only ASX company with a clinical service specialising in unregistered medicines and Real-World Data generation. Emyria has also developed a comprehensive MDMA-assisted therapy protocol that can now support specialists.

Further, Emyria is also leading a wave of future innovation via our active MDMA-inspired drug discovery program in partnership with the University of Western Australia.

We believe the TGA's decision will allow Emyria – and its partners – to build a stronger evidence base for treating mental health conditions with psychedelics and make a large and positive impact for patients globally.

- This release has been approved by the Board of Emyria. -

FOR FURTHER INFORMATION

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UPCOMING MILESTONES

ULTRA-PURE CBD — CLINICAL PROGRAMS

MDMA-INSPIRED — PRE-CLINICAL + THERAPY PROGRAMS

"direct-to-consumer"	*"prescription medicine"*	New Drug Discovery	MDMA-assisted therapy
Formulation optimisation (RX5) ✓	**Formulation optimisation (RX7)** ✓	**Continuous creation & screening** ✓	**Protocol developed** ✓
Phase 1 study done ✓	**Phase 1**	**First patent family** filed ✓	**Clinical partnerships** ✓
Phase 3 commencement ✓	Pre-IND **(FDA)**	**US-focused** preclinical program ✓	**Real-World Data system** ✓
Regulatory submission	**Pivotal** trials	**Metabolic** studies ✓	**MDMA supply secured**
Commercial strategy **Australia**		**Lead** selection	**Therapist training**
Commercial strategy **Europe**		**Phase 1** trials	**First** patient
Commercial strategy **USA**		**Global** commercial strategy	**Global** commercial strategy

ABOUT EMYRIA | emyria.com

Emyria Limited is a clinical drug development and care delivery company focused on accelerating drug development and improving patient outcomes in neuroscience and mental health via:

- **Drug Development:** Multiple, proprietary, Ultra-Pure cannabinoid dose forms suitable for registration against multiple indications. Emyria's first dose form, EMD-RX5, is in Phase 3 trials.
- **New Drug Discovery:** Inspired by MDMA, Emyria is developing one of the world's largest libraries of MDMA-like compounds with partner, the University of Western Australia.
- **Proprietary Real-World Data (RWD):** Emyria gathers robust and ethically-sourced data with patients cared for at Emyria's own specialist clinical service (Emerald Clinics). Emyria RWD can help support drug development and care model improvement.

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.

1. https://www.tga.gov.au/sites/default/files/2023-02/notice-of-final-decision-to-amend-or-not-amend-the-current-poisons-standard-june-2022-acms-38-psilocybine-and-mdma.pdf *accessed 05 Feb 2023*
2. https://www.tga.gov.au/news/news/final-decision-scheduling-cannabis-and-tetrahydrocannabinols-frequently-asked-questions
3. See ASX releases 05 May 2021, 29 June 2021
4. See ASX releases 05 August 2021, 09 May 2022,
5. See MDMA-inspired drug discovery webinar posted 13 October 2022

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(ASX:EMD)

TGA RESCHEDULING AND EMYRIA'S MDMA PROGRAMS

February 2023

Michael Winlo, CEO

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Presentation release authorised by Michael Winlo, CEO and Managing Director

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WHAT DECISION DID THE TGA MAKE ON FEB 03?

From July 1st, 2023 the TGA will add psilocybin and MDMA to Schedule 8, permitting their use as Controlled Drugs but only for treatment resistant depression (TRD) and post-traumatic stress disorder (PTSD), respectively.

TGA is the first major regulator in the world to recognise the growing and substantial body of evidence supporting the therapeutic use of MDMA and psilocybin, when provided alongside therapy, for PTSD and Major Depression respectively. The regulatory change creates a new treatment possibility for patients suffering from major mental health challenges and provides a path to registration and reimbursement for drug developers.
MDMA-assisted therapy is expected to be the first psychedelic-assisted therapy to achieve FDA registration in 2024. [1]

MDMA & Psilocybin to S8 | 01 July 2023

WHY EMYRIA SUPPORTS RESCHEDULING?

In recognition of the rising burden of major mental health disorders and the growing Emyria has supported the rescheduling of MDMA and psilocybin since it was first tabled by Mind Medicine Australia in 2020 [2]. Compelling clinical evidence supporting the controlled therapeutic use of these compounds, together with supportive therapy, has been demonstrated in pioneering research conducted by the Multidisciplinary Association for Psychedelic Studies (MAPS) and others. [3]

Via Emyria's clinical service subsidiary, Emyria has provided care using unregistered treatments to over 8,000 patients with unmet needs. Mental health challenges, including PTSD, are some of the most commonly referred clinical indications. Emyria has first-hand experience caring for patients with these conditions and recognises the great need for new, integrated approaches to address these challenging conditions.

EMYRIA'S COMMITMENT:

Emyria recognises there is a need for training and education programs to prepare healthcare professionals to use psychedelics in therapeutic settings and to provide appropriate support and care to patients. In addition, long-term safety and cost-effectiveness studies are required and, possibly, changes in healthcare system dynamics and funding mechanisms. Emyria believes overcoming these challenges represent opportunities that require partnerships, a commitment to evidence-based and evidence-generating medicine and the highest ethical standards.

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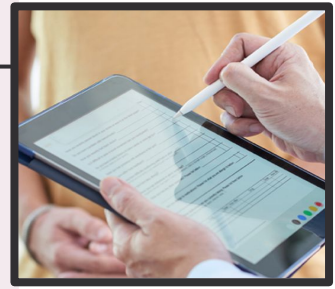
1. https://www.drugdiscoverytrends.com/maps-predicts-fda-approval-for-mdma-assisted-therapy-in-2024/
2. See ASX releases 19 Nov 2020 & 01 Oct 2021
3. https://maps.org/2022/11/17/mapp2-second-maps-sponsored-phase-3-trial-of-mdma-assisted-therapy-for-ptsd-completed/

EMYRIA IS READY TO SUPPORT PATIENT ACCESS & INNOVATION:

	TGA REQUIREMENTS	EMYRIA'S READINESS
AUTHORISED PRESCRIBER DETERMINATION REQUIRES ETHICS APPROVAL	Outside of clinical trials, after July 1st, patient access to MDMA or psilocybin is only possible via prescription from an "Authorised Prescriber" - a qualified psychiatrist with a special authorisation from an accredited **Human Research Ethics Committee ('HREC').** The HREC must review the suitability of the practitioner, the justification for the clinical request on a per indication, per drug basis and the appropriateness of **detailed care plans** to monitor each patient under treatment.	**Emerald Clinics** (Emyria's active clinical service subsidiary) ha initiated, and continues to report for, **16 successful Authorised Prescriber applications.** **Emyria** is familiar with the submission process and ongoing reporting requirements for Authorised Prescribers.
EVERY AUTHORISED PRESCRIBER APPLICATION REQUIRES DETAILED CARE PLANS	Each request for "Authorised Prescriber" status must provide detailed plans and protocols for managing: ***Patient selection & consent:*** The TGA has restricted the use of MDMA for treatment resistant Post Traumatic Stress Disorder (tr-PTSD). Patients must be appropriately diagnosed, screened for contraindications, and appropriately consented in order to receive MDMA-assisted therapy. ***Supportive therapy:*** Unlike traditional psychopharmacology, supportive therapy by specially trained professionals is deeply intertwined and integral to MDMA-assisted therapy. Careful preparation of the physical environment under which therapy takes place is also crucial as sessions can last many hours. ***Treatment & safety monitoring:*** APs must demonstrate adequate controls are in place for patient monitoring before, during and after treatment as well as a mechanism for reporting adverse events.	Emyria has developed a detailed **Phase 2B clinical trial** protocol for MDMA-assisted therapy that will support Authorised Prescriber requests and safe patient care. ***Patient selection & consent:*** Emyria is managing an ethical patient consent process for 8,000+ patients with unmet needs prescribed unregistered medicines. ***Supportive therapy:*** Emyria has deep relationships with trained psychotherapists and specialist clinics. ***Treatment & safety monitoring:*** Emyria has developed extensive digital infrastructure that can support clinical outcomes tracking, safety assessments and adverse event reporting for MDMA-assisted therapy. Through this system, Emyria has compiled one of the world's largest Real-World Data sets on cannabinoid therapy and is positioned to support the same for MDMA.
DRUG IMPORTATION & SUPPLY IS TIGHTLY REGULATED	As a "controlled substance" the importation, handling and distribution of MDMA and psilocybin will be tightly regulated by the Office of Drug Control ('ODC'). Only specially credentialed organisations with the appropriate licenses will be able to handle GMP-grade MDMA.	Emyria holds the required licences from the ODC and has established close relationships with all of the required groups (couriers and pharmacies) as well as GMP manufacturers to manage a supply of MDMA to partners.



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ADVANCING MDMA | THERAPEUTIC *INNOVATION* & COMMERCIAL OPPORTUNITIES

Emyria will apply its experience in facilitating SAFE ACCESS to unregistered treatments and developing novel medicines to SUPPORT the delivery of MDMA-inspired therapies

1. PROVIDING CLINICAL & DATA INFRASTRUCTURE

THE NEED: Specialist psychiatrists applying to become "Authorised Prescribers" must provide evidence of detailed risk management plans that cover patient selection, consent and monitoring. They must also work closely with specially-trained therapists.

THE OPPORTUNITY: Provide the clinical and data monitoring infrastructure, protocols and drug supply chain to establish a national, decentralised network of private psychiatrists and therapists to deliver MDMA-assisted therapies.

2. DEVELOPING & REGISTERING NEW DRUGS, INSPIRED BY MDMA

THE NEED: Not all patients are suitable for MDMA-assisted therapy and many, major unmet neuropsychiatric disorders remain.

THE OPPORTUNITY: Take MDMA as inspiration to generate multiple, novel drug candidates that are neurologically active in order to address major unmet needs in mental health and neurological disorders. This work is well underway with more than 140 novel drug candidates developed under three leading series:

1. *"Next-generation MDMA"* (i.e. faster acting MDMA-like medicine suitable as a next-generation psychedelic-assisted therapy)
2. Treatments for neurological disorders, particularly movement disorders
3. Other treatments targeting novel monoamine oxidase-transporter pathways

MDMA-ASSISTED THERAPY PROTOCOL | EMDMA-001

Novel RESEARCH and specialised training are needed because of the way MDMA-assisted therapy is delivered. The treatment is UNLIKE traditional psychotherapy or psychopharmacology. 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.

MDMA-INSPIRED DRUG DISCOVERY | WHAT'S NEXT?

NEW DRUG DISCOVERY BACKED BY **UWA RESEARCH**

THE UNIVERSITY OF WESTERN AUSTRALIA

UWA Researcher Dr Joelie Loh | working on Emyria's Program **"New Drug Discovery"** in partnership with UWA.

IN THE NEXT 12 MONTHS, EMYRIA INTENDS TO:

- **Deliver results** from multiple preclinical programs on select MDMA analogues
- **Select leads** by proof-of-concept efficacy studies in animal models
- **Expand** the MDMA-analogue library (already 140+ compounds)
- **File** additional patent families and pursue commercialisation discussions

MDMA-A

Ongoing creation and in vivo screening

Hit-to-lead identification and dose form development

Preclinical Screening and Toxicology

Phase 1 Clinical Trials

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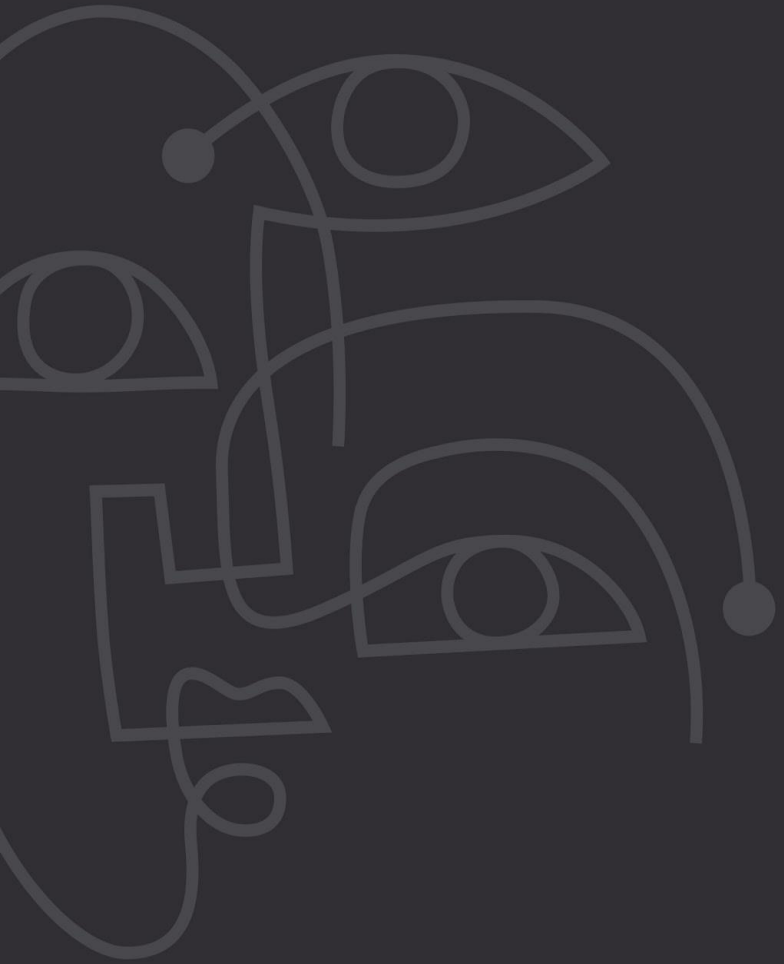

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