ASX Announcement
10 Jul 2023

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

First Patient Recruited to Emyria's MDMA-Assisted Therapy Trial

HIGHLIGHTS

First patient recruited for Emyria's Phase 2B, MDMA-assisted therapy trial (**EMDMA-001**) for Post-Traumatic Stress Disorder (**PTSD**)

MDMA importation has commenced following the receipt of key approvals from the Office of Drug Control (**ODC**) and the Australian Therapeutic Goods Administration (**TGA**)

EMDMA-001 will assess efficacy, safety and cost effectiveness of MDMA-assisted therapy as a potential treatment for PTSD at Emyria's newly acquired psychological trauma treatment - centre - The Pax Centre [1] (**Pax**) and support Authorised Prescriber applications for Emyria's psychiatrists

Data gathered from EMDMA-001 will form the beginning of a comprehensive national patient data registry to support safety monitoring, research and payer engagement

Emyria Limited (ASX: EMD) (**Emyria**, or the **Company**) is pleased to announce the successful recruitment and consent of the first patient for Emyria's innovative Phase 2B, MDMA-assisted therapy trial for PTSD; with the first treatment expected in August.

Building on the momentum of Emyria's recent acquisition of The Pax Centre, this pivotal first step supports Emyria's mission to pioneer the development and delivery of MDMA-assisted and psilocybin-assisted therapies for patients facing major mental health challenges.

The EMDMA-001 trial has been carefully designed to evaluate the safety, efficacy and cost effectiveness of MDMA-assisted therapy for PTSD. The trial is expected to generate crucial data to help fortify Emyria's leadership in delivering psychedelic-assisted therapy within a multidisciplinary, wraparound clinical service.

This study will support Authorised Prescriber applications for Emyria's team of highly skilled psychiatrists - allowing Emyria to establish a commercial delivery model.

To ensure meticulous supportive care and comprehensive monitoring for each participant, Emyria will carefully staggering recruitment. Additional patients have already been identified from Pax's existing database, and extensive in-bound interest, promising a robust participant base for our trial.

The study launches a unique patient data registry using Emyria's cutting edge data platform - Palantir Foundry.

Emyria has secured a key importation licence from the Office of Drug Control (**ODC**) for the patient-ready MDMA to be used in our EMDMA-001 trial. Obtaining the importation licence for regulated substances like MDMA is a significant accomplishment that highlights Emyria's dedication and regulatory acumen.

According to Australian regulations, the import and export of substances such as MDMA are strictly prohibited, unless accompanied by a licence and permit issued by the Drug Control Section (**DCS**). Successfully securing these permissions demonstrates Emyria's commitment to comply with stringent regulations and our capability to navigate complex regulatory environments. This not only signifies a pivotal step forward for our EMDMA-001 trial but also emphasises our capability to deliver on our promise of providing innovative, regulatory-compliant mental health treatments.

EMDMA-001 Trial Details

ITEM	DESCRIPTION
Primary Endpoint(s)	Safety and cost effectiveness measures.
Secondary Endpoint(s)	Comprehensive suite of clinical and quality of life measures.
Product Status	MDMA has been recently rescheduled to a Schedule 8 controlled medicine for the treatment of PTSD. The MDMA used in the study is an unregistered GMP-grade medicine. There are no approved MDMA medications.
Treatment Method, Route, Frequency, Dose Levels, Expected Duration	Participants will receive up to three MDMA-assisted therapy sessions over three months and followed up for 12 months post treatment. Treatment sessions will be supplemented by extensive preparation and integration sessions before, during, and after.
Number of Trial Subjects & Selection Criteria	The trial is designed with no maximum number of participants. Emyria has secured sufficient MDMA supply for an initial cohort of up to 70 adult participants, all of whom have been diagnosed with PTSD.
Trial Locations	The trial will take place at Emyria's Pax Centre but it is possible to add additional sites once suitably prepared.
Trial Standard	The study is being conducted in accordance with international best practice standards and fully complies with the principles of Good Clinical Practice (**GCP**), as outlined by the International Council for Harmonisation (**ICH**).

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THE OPPORTUNITY FOR PSYCHEDELIC-ASSISTED THERAPY

Psychedelic-assisted therapy is an innovative new treatment approach showing great promise for the most challenging mental health conditions like PTSD [2] and treatment-resistant Depression (**tr-D**).[3] The recent rescheduling of MDMA and psilocybin as controlled medicines by the TGA from July 1st 2023 [4] offers exciting opportunities for broadening the clinical application of these new treatments.

The important and rigorous regulatory compliance and implementation required to administer these new treatments will restrict their availability to highly specialised and appropriately trained clinical services and a cost-effective delivery model needs to be established.

THE EMYRIA + PAX SOLUTION UTILISING PALANTIR FOUNDRY

Emyria has long demonstrated excellence in developing complex care protocols, managing clinical studies, and working with newly rescheduled medicines. This is best exemplified by its existing clinical service, Emerald Clinics [5]. This service has successfully treated thousands of patients with pharmaceutical-grade cannabinoids and simultaneously gathered robust clinical data using the advanced data capture, analysis and machine learning platform, Palantir Foundry [6, 7]. Emyria's data assets have also guided personalised care plans as well as help launch and commercialise [8] several innovative drug development programs.

By acquiring The Pax Centre, Emyria significantly expands its care team in mental health by adding world-class, fit-for-purposes mental healthcare facilities and a multidisciplinary team of 20 mental health professionals covering psychiatry, mental health nursing, clinical psychology, counselling, social work, occupational therapy and chiropractic care.

The Company plans to integrate key operations of Emyria's GP-led service, Emerald Clinics, within the established framework of the Pax Centre. The goal is to generate stronger and broader clinical service revenue synergies while also establishing a global centre of excellence in the delivery and development of new and innovative therapies for complex mental health and neuropsychiatric conditions such as psychedelic-assisted therapy.

Uniquely, the Emyria + Pax model will provide a **suite of integrated clinical services** thereby circumventing the limitations of standalone single treatment clinics. This ensures those with severe complex mental health needs have wrap-around care to focus not only on the disease but on recovery, rehabilitation, care and well-being of patients, carers and family.

READINESS FOR PSYCHEDELIC-ASSISTED THERAPY

Emyria and the Pax Centre are already well advanced to deliver psychedelic-assisted therapy having:

- Secure supply of patient-ready MDMA [9]
- Trained team of therapists and clinicians [10]
- Ethics-approved care protocol for MDMA-assisted therapy [1]
- Established an advanced patient data registry [6]

Emyria and the Pax Centre are now developing care models for psilocybin-assisted therapy for tr-D as well as the additional clinical trial protocols to broaden and expand the knowledge of how these new interventions work for additional indications.

RECENT TRACTION & UPCOMING MILESTONES

CLINICAL PROGRAMS

"Direct-To-Consumer"	*"Prescription Medicine"*
Formulation optimisation (RX5) ✓	**Formulation optimisation (RX7 > RX9)** ✓
Phase 1 study done ✓	**Preclinical Screening Program for Pain**
Phase 3 commencement ✓	**Phase 1**
Regulatory submission	Pre-IND **(FDA)**
Commercial strategy **Australia** ✓	**Pivotal** trials
Commercial strategy **Europe**	
Commercial strategy **USA**	

PRE-CLINICAL + THERAPY PROGRAMS

New Drug Discovery	Psychedelic-Assisted Therapy
Continuous creation & screening ✓	**Protocols developed** (MDMA) ✓
First patent family filed ✓	**Clinical partnerships** ✓
US-focused preclinical program ✓	**Real-World Data system** ✓
Metabolic studies ✓	**MDMA supply secured** ✓
Lead selection	**Therapist training** ✓
Phase 1 trials	**Ethics approval** (MDMA) ✓
Global commercial strategy	**Protocol developed** (psilocybin)
	Psilocybin supply secured
	Authorised Prescriber (MDMA)
	Authorised Prescriber (psilocybin)

This release has been approved by the Managing Director of Emyria.

FOR FURTHER INFORMATION

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The Advantages Of Emyria's Integrated Service For The Delivery Of Psychedelic Therapies:

1. **Safety and Professional Expertise:** Given the potent and often unpredictable nature of psychedelic substances, it's essential to administer them in a controlled, professional environment. Patients can experience intense psychological shifts during these therapies, requiring expert oversight and immediate response capabilities to manage any adverse reactions. An integrated clinical service ensures that this safety and expertise is consistently maintained.

2. **Continuity of Care:** Psychedelic-assisted therapy isn't a one-off treatment; it's a journey that requires pre-session preparation, the session itself, and post-session integration work. Delivering this therapy within a multidisciplinary service facilitates a seamless continuity of care, ensuring that all stages of the treatment are harmoniously interconnected.

3. **Comprehensive Understanding:** In an integrated clinical service, all aspects of a patient's health - physical, psychological, and social - are considered. This comprehensive view is crucial for the success of psychedelic-assisted therapy, as it allows for a deeper understanding of the patient's condition and tailoring the therapeutic process accordingly.

4. **Psychotherapeutic Support:** Psychedelic experiences often unveil deeply embedded psychological content that can be difficult for patients to process. An integrated service with mental health professionals such as psychiatrists, psychotherapists, and social workers can provide essential support during and after these intense experiences, enhancing the therapy's efficacy.

OUR DELIVERY ADVANTAGE | DATA DRIVEN, MULTIDISCIPLINARY CARE

Service Model for Mental Health	Key Strengths	Key Limitations	Emyria Advantages
GP Clinics	Accessible, generalised care	Limited support; not specialised	✓ Our model provides specialised care with robust support
Specialists	High-level, specialised care	Often do not address physical health	✓ Our model offers holistic, multidisciplinary care covering mental & physical health
***"Single service"* clinics** (eg. "Ketamine Clinics")	Specialised service	Referral risk for clinicians. *"Where do my patients go if treatment fails?"*	✓ Our model offers a suite of services before, during & after care
Academic & Research Centers	Cutting-edge research and treatments	Not focused on scalable, cost effective delivery	✓ Our model combines innovative approaches with scalability and cost effective delivery
Emyria Model	Multidisciplinary, data-driven, scalable; Care **before**, **during** & **after** therapy	---	✓ **Delivers comprehensive, data-driven care at scale; incorporates next-generation therapy delivery & development**

ABOUT EMYRIA | emyria.com

- **Emyria Limited** is a clinical services and drug development company with a focus on revolutionising patient outcomes in neuroscience and mental health via:
  - **Clinical Service Delivery:** With Emerald Clinics, and the recent acquisition of the Pax Centre, a leading psychological trauma center, Emyria delivers evidence-based and emerging therapies for mental health and other unmet needs.
  - **Proprietary Real-World Data (RWD):** Through its advanced data platform powered by Palantir, Emyria collects robust and ethically-sourced Real-World Data to improve its care models and support its distinct therapy and drug development initiatives.
  - **Drug Discovery & Development:** Guided by its RWD, Emyria is developing several proprietary Ultra-Pure cannabinoid dose forms and advancing them towards registration. In parallel, we are establishing one of the world's largest libraries of MDMA-like compounds in partnership with the University of Western Australia.

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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.

ABOUT The Pax Centre | paxcentre.com.au

The Pax Centre specialises in treating individuals grappling with the psychological impacts of traumatic experiences. Our treatment approach is highly personalised, addressing a wide range of mental health issues, from PTSD and depression to anxiety disorders and substance abuse, often stemming from various life traumas.

Complex trauma, characterised by repeated, relational traumatic events often occurring during developmental stages, requires specialised attention due to its pervasive and lasting impact. In these cases, The Pax Centre prioritises early diagnosis and evidence-based treatments.

We also focus on proactive strategies for health expansion and personal growth, empowering our clients with skills and tools to improve wellbeing and performance. At the Pax Centre, we believe in transforming lives through focused, evidence-based mental health care

ABOUT Emerald Clinics | emeraldclinics.com.au

Emerald Clinics is an Australian-based, patient-centric clinical services specialising in providing treatments for patients with complex and chronic conditions, where traditional therapies might not have yielded satisfactory results.

Leveraging our deep expertise with unregistered medicines, such as cannabinoids, we strive to pioneer and personalise care for our patients. Our robust, ethically-sourced data collection methods underpin our commitment to improving patient outcomes and advancing healthcare innovation.

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.