emyria

Delivering & developing new treatments for mental health & neurological conditions

ASX Announcement | 05 April 2024

Emyria Expands Authorised Prescriber Team with First Female Specialist Approved for MDMA-Assisted Therapy for PTSD

HIGHLIGHTS

Emyria's second psychiatrist receives "Authorised Prescriber" (AP) approval from the TGA.

Authorisation reflects Emyria's dedication to expanding mental health care treatment options under the strict regulatory, ethical, and safety frameworks mandated by the TGA.

Emyria's second AP is believed to be the first, and currently only, female Authorised Prescriber for MDMA-assisted therapy in Australia.

An additional AP increases Emyria's capacity for trials and patient care, and aligns with current clinical facility expansion efforts.

Emyria Limited (ASX: EMD) ("Emyria", or the "Company") focused on delivering and developing new treatments for mental health and select neurological conditions, is pleased to announce the Company's first female psychiatry specialist has been granted "Authorised Prescriber" status by the Therapeutic Goods Administration (TGA). The authorisation enables the prescribing of MDMA according to an ethics committee endorsed care model developed by Emyria [1] and within the strict regulatory framework established by the TGA for the treatment of Post-Traumatic Stress Disorder (PTSD). [2]

Market Potential - Unmet Needs in Post-Traumatic Stress Disorder (PTSD) Treatment:
PTSD affects approximately 1 million Australians [3]. With up to one third of patients failing to benefit from conventional therapies, there is a growing need amongst patients and clinicians for more effective treatments. MDMA-assisted therapy (MDMA-AT) is being evaluated as a treatment for PTSD and multiple Phase 3 clinical trials have been conducted by MAPS in the USA. [4, 5] However, very few clinical services can provide and evaluating these therapies given the complex coordination required.

Emyria is currently evaluating MDMA-AT therapy for PTSD in an ethics-approved clinical trial (EMDMA-001) as well as under the Company's active Authorised Prescriber program via a recent binding research service agreement with charity Reach Wellness to evaluate the treatment for first responders with PTSD. [6]

Commercialisation Strategy
Emyria is at the forefront of addressing the significant unmet need in PTSD treatment and has invested substantially over the past few years in establishing the comprehensive support infrastructure required to deliver and evaluate new treatments like MDMA-AT. The Company's expertise comprises navigating regulatory frameworks, conducting clinical trials, and developing ethical, patient-centred care models for direct patient care.

Commercialisation Strategy (Continued)
Additional Authorised Prescribers on staff directly supports the Company's efforts by providing more capacity for clinical trials, patient care and associated service revenues.

To capitalise on its unique suite of capabilities, Emyria is exploring the potential of a scalable commercialisation strategy that involves licensing its model via clinical partnerships with mental health care providers across Australia as well as engaging with large health payers with the goal of helping improve access to new treatments for patients that may benefit.

Expansion Model
Emyria's infrastructure supports the delivery and evaluation of multiple psychedelic-assisted therapies. Recognising the potential of various psychedelic-assisted approaches in treating a range of mental health conditions, Emyria plans to expand its treatment portfolio to include ketamine- and psilocybin-assisted therapies in the longer term.

There are currently no products containing psilocybin or MDMA included in the Australian Register of Therapeutic Goods (ARTG) that have been evaluated by the TGA for safety, quality and efficacy. However, there is now sufficient evidence that psilocybin and MDMA will potentially be effective in the treatment of treatment-resistant depression (TRD) and PTSD, respectively, for certain patients. In particular, clinical trials have shown promise when they are used in combination with psychotherapy conducted in strictly controlled medical settings.

By leveraging the Company's existing capabilities and infrastructure, Emyria aims to become a comprehensive provider of specialist-led, legal, psychedelic-assisted therapies where allowed and indicated.

Long-term Innovation Pipeline
The Company is utilising the revenues and data generated from its clinical services to support proprietary innovation efforts including new care models and novel drug development. The Company is currently advancing an ambitious MDMA analogue development program with global partners, the University of Western Australia (UWA) and the National Institute of Health (NIH) in the USA.[7] The Company has also been given a clear search report from the international patent examiner [7], indicating the novelty and potential patentability of a massive library of novel MDMA analogues with the potential to become a new treatments for PTSD.

Dr. Michael Winlo, CEO, commented: *"Our second authorisation demonstrates Emyria's commitment and ability to increase our service capacity to evaluate emerging treatments for mental health within the strict regulatory frameworks established by the TGA.*

"Our initial focus is on evaluating MDMA-assisted therapy for PTSD. With the female incidence of PTSD almost twice that of males, we are pleased to support an approach that acknowledges and addresses the specific needs of women suffering from PTSD by supporting the first approved female Authorised Prescriber for MDMA-AT.

"We are excited to be building a unique company that is both directly helping patients today, while also applying its revenue and unique data insights to support a long-term innovation agenda. "

Risks associated with the use of Psilocybin, MDMA and Ketamine [8]

All medicines carry risks and specialist prescribers, such as registered psychiatrists, are best placed to assess the suitability of a new medication against a patient's individual circumstances and medical history before proceeding. Adverse effects of psilocybin can include temporary increase in blood pressure and a raised heart rate. Adverse effects of MDMA include high blood pressure, increased pulse rate, faintness, and panic attacks, and in some rare cases it can cause loss of consciousness or trigger seizures. Other side effects include involuntary jaw clenching, decreased appetite, restless legs, nausea, headache, sweating and muscle/joint stiffness. These effects of psilocybin and MDMA are unlikely at low doses in the treatment regimens used in psychedelic-assisted psychotherapy while appropriately managed in a controlled environment with direct medical supervision.

Ketamine has potential to cause acute physical, psychiatric, psychotomimetic and cognitive side effects following a single dose and cumulative side effects resulting from repeated dosing. The majority of studies of ketamine in depression have examined side effects only acutely and after a single dose, with limited studies examining safety in repeated doses. Acute physical adverse effects of ketamine include hypertension, sedation, nausea or vomiting, headache, poor coordination, poor concentration, dizziness, blurred vision, and restlessness. The potential of ketamine to induce acute hypertension, lower urinary tract dysfunction and interstitial cystitis, and alter hepatic function, and noting that ketamine is metabolised by the liver, warrant screening for relevant pre-existing conditions.

References:

1. See ASX release 30 October 2023
2. https://www.tga.gov.au/news/media-releases/change-classification-psilocybin-and-mdma-enable-prescribing-authorised-psychiatrists
   The availability of these products is subject to the safety and efficacy of the products being tested through clinical trials. Emyria makes no representations or warranties as to the safety or efficacy of the products or the products' ability (or the ability of its key compounds) to be used in the treatment of indications such as PTSD. There are currently no approved products containing MDMA that the TGA has evaluated for quality, safety and efficacy. Consumers should be aware that MDMA may cause side effects, as set out in the "Risks associated with the use of MDMA" in this announcement.
3. https://www.phoenixaustralia.org/news/ptsd-awareness-day-2022/
4. Mitchell, J.M., et al. MDMA-assisted therapy for severe PTSD: Nat Med 27, 1025–1033 (2021)
5. Mitchell, J.M., et al. MDMA-assisted therapy for moderate to severe PTSD: Nat Med (2023). https://doi.org/10.1038/s41591-023-02565-4
6. See ASX release 02 April 2024
7. See ASX release 28 February 2024
8. https://www.ranzcp.org/getmedia/75baa529-2b71-419f-993a-2ff64ede50fe/cm-use-of-ketamine-in-psychiatric-practice.pdf

This release has been approved by the Board of Emyria.

FOR FURTHER INFORMATION

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Emyria Limited is focused on developing and delivering new treatments for mental health and select neurological conditions through through an integrated model of direct clinical services and drug development:

Emyria Healthcare: Evidence-based treatment for patients not finding relief from conventional care while also helping evaluate emerging new therapies like MDMA-assisted therapy for PTSD [1]

generates

Emyria Data: Robust and ethically-sourced Real-World Data gathered with patients and used to improve Emyria's unique therapy and drug development programs.

informs

Emyria's Pipeline: One of the world's largest libraries of unique MDMA-like compounds developed in partnership with the University of Western Australia seeking new psychedelic-assisted therapies and treatments for neurological diseases as well as highly potent dose forms of Ultra-Pure CBD seeking registration for a range of mental health and neuroscience indications.

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.