

Emyria Selected by Reach Wellness to Lead MDMA - Assisted Therapy Research for First Responders



HIGHLIGHTS

Charity “Reach Wellness” selects Emyria to manage a study of Emyria’s scalable MDMA-assisted therapy (MDMA-AT) program for first responders with Post-Traumatic Stress Disorder (PTSD) together with a support program provided by Reach Wellness.

Reach and Emyria have entered into a binding research study agreement where, subject to fundraising, Reach will subsidise costs of treatment for an initial cohort of 50 qualified first responders amounting to an estimated total of \$1.5 million.

Reach Wellness has initiated a fundraising campaign to cover all treatment and study-related costs for this project; first participant enrolled.

Study to support broader health service and payer engagement by helping demonstrate the safety, effectiveness and scalability of Emyria’s MDMA-AT model.

Emyria Limited (ASX: EMD) (“Emyria”, or the “Company”) investigating new treatments for mental health and select neurological conditions, is pleased to announce it has entered into a binding research study agreement with charity Reach Wellness to manage a pivotal observational study designed to evaluate the effectiveness of Emyria’s MDMA-assisted therapy (MDMA-AT) program, together with a support program managed by Reach Wellness, for first responders with PTSD. The agreement underscores Emyria’s leadership in the evolving field of MDMA-AT research and marks a significant step forward in addressing the unique care and support requirements of first responders suffering from PTSD.

Emyria is at the forefront of mental health treatment innovation, having commenced community-based MDMA-assisted therapy trials in October 2023¹. Its lead psychiatrist has since achieved Authorised Prescriber status², becoming one of the few services nationwide authorised and capable of providing MDMA-assisted therapy for PTSD under the rigorous regulatory oversight and requirements established by the TGA. There are risks associated with the use of MDMA, which are set out at the end of this announcement.

As part of its commitment under the research study agreement, Reach Wellness has embarked on a vital fundraising effort to cover all treatment and follow-up costs for an initial cohort of 50 suitably screened first responders who are struggling with PTSD and eligible for MDMA-AT. This initiative represents a substantial pledge towards mental health care (an estimated \$1.5m) and will help evaluate the potential of new therapies for those who serve and protect us.

Treating PTSD in First Responders

The Emyria-Reach Wellness initiative arises in response to the growing national mental health challenge. Over a million Australians have PTSD ³ with first responders and veterans showing a 60% higher incidence rate ⁴. Traditional treatments may not provide relief for all sufferers, highlighting a need for innovative approaches. MDMA-AT has shown promise as a potential treatment for PTSD in multiple Phase 3 clinical trials conducted in the USA ⁵ and from July 1st 2023, MDMA can be legally prescribed for PTSD by specialist psychiatrists who have obtained Authorised Prescriber status from the TGA ⁶ and who can also demonstrate a capability to provide supportive therapy.

The Emyria and Reach Wellness partnership aims to evaluate the Real-World efficacy and cost benefits of Emyria's MDMA-AT model combined with a tailored support program for an initial cohort of 50 first responders. Consequently, the research study agreement is expected to directly support engagement with major Health Payers while contributing to a broader understanding of these new treatments.

The support from Reach comes as Emyria is in the process of enhancing its capacity for Real-World research by expanding its clinical facilities and increasing its pool of Authorised Prescribers and trained therapists. These investments improve Emyria's ability to develop a scalable and commercially viable MDMA-AT model while Reach's support increases the Company's potential to evaluate new mental health solutions on a wider scale.

Reach Wellness founder, Rick Green: *"First responders keep our communities safe and functioning both locally and overseas. However, these roles can be highly stressful both physically and mentally as is evident by the high rates of PTSD and other mental health challenges."*

"Reach's mission is to fund research and care programs for those who help others first with the generous support of our donors."

"Emyria is one of the most well-prepared research organisations in Australia capable of evaluating MDMA-assisted therapy in real-world settings and we are excited to partner with them on this research program managed within a strictly controlled regulatory environment."



Rick Green, Reach Wellness
Co-Founder, Air Force Veteran,
Current RSL President, Joondalup

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Emyria CEO, Dr Michael Winlo said: *“We are delighted to partner with Reach Wellness to help improve the treatment and support of Australia’s first responders who are impacted by mental health conditions like PTSD.*

“We are committed to evaluating the impact of emerging approaches like MDMA-Assisted Therapy and the team at Reach shares our vision and is committed to backing it financially, with the support of its generous donors.”

A binding research study agreement has been entered into between the parties to advance the trial. Material terms are outlined on Page 4.

A comprehensive fundraising campaign is now underway, managed by Reach Wellness, to raise the estimated \$1.5m required to cover all treatment and study costs for the initial 50 participant cohort.

References:

1. See ASX release 09 Oct 2023
2. See ASX release 10 Jan 2024
3. <https://www.phoenixaustralia.org/>
4. Bryant RA. The nature of PTSD in treatment-seeking first responders. Eur J Psychotraumatol. 2022 Jan 26;13(1):2011602.
5. Mitchell, J.M., et al. MDMA-assisted therapy for moderate to severe PTSD: a randomized, placebo-controlled phase 3 trial. Nat Med (2023) AND Mitchell, J.M., et al. MDMA-assisted therapy for severe PTSD: a randomized, double-blind, placebo-controlled phase 3 study. Nat Med 27, 1025–1033 (2021)
6. <https://www.tga.gov.au/news/media-releases/change-classification-psilocybin-and-mdma-en-able-prescribing-authorised-psychiatrists>

FOR FURTHER INFORMATION

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

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The material terms of the research study agreement are as follows:

Term	3 years
Termination	The parties may terminate for a breach of a material term of the contract.
Research Study	A study to evaluate the costs and benefits of the treatment provided by Emyria in relation to treatment of first responders with a current diagnosis of post-traumatic stress disorder (PTSD).
Obligations	Emyria is responsible for identifying and qualifying candidates and making clinical determinations in the study
Treatment	Emyria's MDMA-assisted therapy model.
Subsidy	In relation to a qualified participant, a contribution of up to \$30,000.00 (or such other amount agreed between the parties from time to time.
Intellectual property	Emyria owns all intellectual property in the observational study, the treatment, and the reports.
Minimum Funding	There is no minimum funding requirement, however, to the extent that Reach Wellness is unable to raise funds, it will not be able to sponsor participants in the study.
Total Funding	Up to \$1,500,000.

Aside from securing funding and ethics approval, there are no other conditions precedent, and it is anticipated that the study will commence before H2, 2024.

The study has strict eligibility requirements. Further, participants in the study are required have a medical referral from their general practitioner and will not be able to participate in the study through contacting Emyria or Reach Wellness directly. Neither Emyria nor Reach advocate the use of MDMA for the treatment of PTSD outside of the research study, or as otherwise prescribed by an authorised prescriber.

Risks associated with the use of MDMA

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 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 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.

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

generates

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

informs

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

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](https://investorhub.emyria.com) Interact with Emyria's announcements and updates by asking questions and comments, which our team can respond to where possible.



ABOUT REACH: reachwellness.org.au (ABN: 50639062472)

Reach Wellness is a Deductible Gift Recipient (DRG) charity, established in 2020 with a mission is to support the health and wellbeing of first responders through direct clinical care support and medical research. Reach Wellness was founded by a distinguished group of ex-servicemen, business and not-for-profit leaders. Their collective vision and commitment underpin the "First Relief for those First to Respond" campaign, designed to help evaluate promising new treatments and support options for our community's heroes.

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.