emyria

Developing and delivering new treatments for mental health & neurological conditions

ASX Announcement | 04 February 2025

Emyria Announces Promising 3 Month Follow-Up Clinical Results for PTSD Program

HIGHLIGHTS
Interim analysis at three months post-treatment for the first eight patients completing Emyria's MDMA-assisted therapy (MDMA-AT) program for PTSD confirms a sustained and clinically significant reduction in PTSD symptoms, with PCL-5 scores decreasing by an average of 29.6 points from Baseline to the 3-month follow-up.
Patients also confirms a statistically significant and sustained improvement in quality of life, with ReQoL-10 scores increasing by an average of 23.5 points from Baseline to the 3-month follow-up underscoring the lasting impact of MDMA-assisted therapy on both symptom reduction and overall well-being.
Emyria's program continues to expand with Real-World Data driving program refinement and active engagement with private hospitals and payers to support expansion and improve access.
Findings to be presented today at the **Euroz Healthcare Forum** (Tuesday, February 4th). Full presentation follows this announcement.

Emyria Limited (ASX: EMD) ("Emyria", or the "Company") developing and delivering new treatments for mental health and select neurological conditions, is pleased to share promising interim clinical results from its MDMA-assisted therapy (MDMA-AT) program for Post-Traumatic Stress Disorder (PTSD). [1]

Analysis of an initial cohort of eight patients with moderate to severe PTSD reported on 02 September 2024 [2] —all of whom had limited relief from standard treatments—demonstrate continued improvement in patient outcomes three months post-treatment.

These further follow-up results reinforce the potential of Emyria's program to deliver durable clinical benefits and address significant unmet needs in PTSD care.

Dr. Jon Laugharne, Emyria's lead psychiatrist, commented: *"It's encouraging to see that patients continue to experience meaningful improvements in PTSD symptoms and overall well-being even months after completing treatment. These sustained benefits suggest that MDMA-assisted therapy has the potential to create lasting impacts for individuals who have struggled with severe and treatment-resistant PTSD. The data reinforces what we've observed in our clinic—MDMA-AT is not just reducing symptoms but helping patients reclaim their lives."*

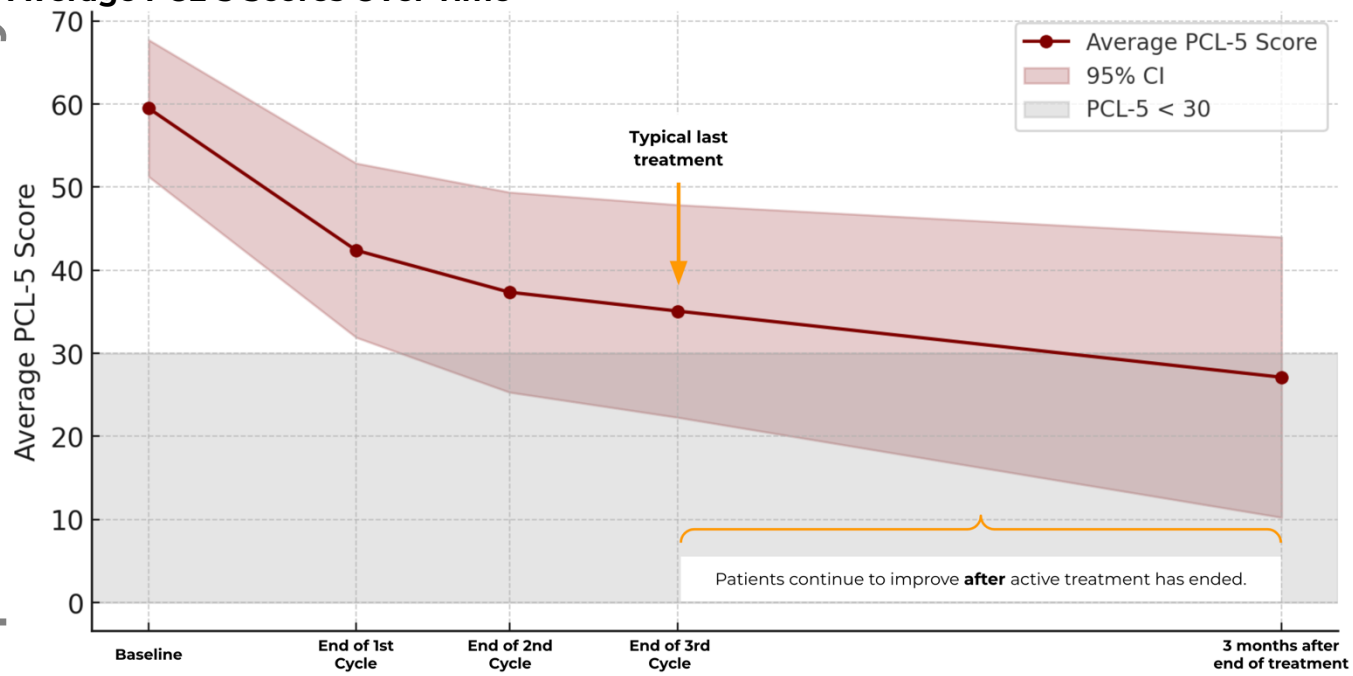
A detailed program overview is provided below.

Significant PTSD Symptom Reduction

Interim analysis reported on 02 September 2024 revealed that Emyria's MDMA-AT program achieved a significant per-patient reduction in PCL-5 scores—a critical measure of PTSD severity—demonstrating that patients experience significant symptom relief at the conclusion of MDMA-Assisted Therapy ("end of 3rd cycle).

Encouragingly, in the three-month follow-up analysis, participants continued to achieve further symptom improvements (a reduction in PCL-5 scores with the average PCL-5 for this population falling below 30, a key threshold indicating substantial symptom reduction. Improvements between baseline (Start of treatment) and the 3-month observation were also statistically significant.

Average PCL-5 Scores Over Time



X-Axis shows "visit type" with spacing corresponding to the average time elapsed between visits.

Figure 1: Mean Percentage Improvement in PCL-5 Scores

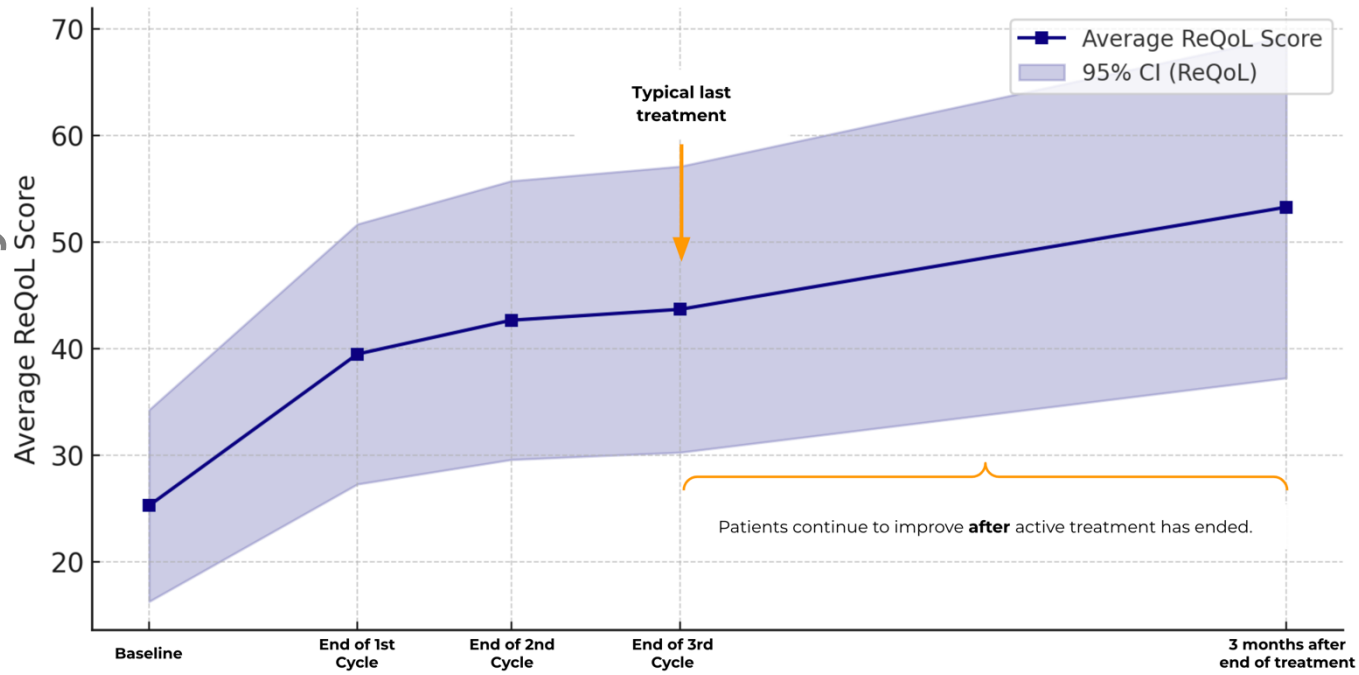
This chart illustrates the mean percentage improvement in PCL-5 scores among an initial cohort of 8 patients who completed MDMA-assisted therapy (MDMA-AT) for PTSD comparing their assessment taken before treatment ("Baseline") to 3 months after the end of active treatment in the program. The continuing reduction in PCL-5 scores demonstrates the effectiveness and durability of Emyria's program in alleviating PTSD symptoms.

The PCL-5 is a self-administered, 20-item self-report tool used to measure PTSD symptoms according to diagnostic DSM-5 criteria (Diagnostic and Statistical Manual of Mental Disorders, 5th Edition). [3]

- **Mean Change in PCL-5 Scores (from baseline to 3 months post treatment):** 29.6 points
- **Paired t-test**: p-value = 0.008 (statistically significant improvement)

Significant Quality of Life Enhancements
Additionally quality-of-life – as measured using the ReQoL assessment – further improved after treatment by an additional average of 10 points, highlighting the broad impact of Emyria's MDMA-AT on patients' overall well-being.

Average ReQoL Scores Over Time



X-Axis shows "visit type" with spacing corresponding to the average time elapsed between visits.

Figure 2: Mean Percentage Improvement in ReQoL Scores
This chart shows the mean percentage improvement in ReQoL scores from baseline to post-treatment for an initial cohort of 12 patients treated with MDMA-AT for PTSD. The enhancement in quality-of-life measures emphasises the broad ability of the program to significantly improve patients' overall well-being alongside symptom reduction.

The ReQoL is a patient-reported outcome measure covering domains such as wellbeing, functioning, and personal recovery, allowing patients to express how their mental health impacts their daily lives and overall quality of life. [4]

- **Mean Change in ReQoL Scores from baseline to 3 months post treatment):** -23.5 points
- **Paired t-test:** p-value = 0.006 (statistically significant improvement)

Program Overview
Emyria's 6-16 week MDMA-AT program involves 90+ hours of therapy, including screening, preparation, supervised dosing, and integration. On average, active treatment spans 106 days, ensuring a structured and personalised approach.

Cohort Insights & Treatment Response
- 8 patients (6 males, 2 females, aged 27-62, avg. 45 years); no control group
- Baseline PCL-5 scores: 32-78 (avg. 58), indicating severe PTSD
- 100% completion rate; 2-3 supervised dosing sessions tailored to symptom progression
- 60% average symptom reduction, with 40% of patients achieving a 50%+ improvement

Safety & Tolerability
- Mild, transient side effects (1 in 4 patients) including temporary high blood pressure, nausea, or jaw clenching
- All side effects were self-limiting and effectively managed in a controlled clinical setting

Significant PTSD Symptom Reduction & Unmet Market Need

PTSD remains a debilitating and difficult-to-treat condition, affecting at least 7% and as much as 11% [5] of adults, with many patients experiencing limited relief from existing treatments like antidepressants and cognitive behavioural therapy (CBT). There is a clear and urgent need for more effective interventions, particularly for the 800,000 Australians who could benefit from breakthrough therapies like MDMA-assisted therapy (MDMA-AT). [6]

Emyria's MDMA-AT program has demonstrated a consistent and sustained clinically significant reduction in PTSD symptoms, with patients experiencing an average PCL-5 score decrease from approximately 60 at baseline to below 30 at the 3-month follow-up, a key threshold indicating substantial symptom relief. Encouragingly, the decline in symptom severity continued beyond the active treatment phase, reinforcing the potential for long-lasting therapeutic benefits.

In addition, quality of life scores continued to improve following treatment as measured in the ReQoL assessment.

These results suggest the long-term potential of MDMA-AT to fill a critical gap in PTSD care for patients who have exhausted conventional treatment options.

Emyria is strategically positioned to lead the way in delivering and scaling this therapy, as well as using our Real-World Data to engage substantial funding support from private health insurance and government funding bodies to ensure more patients have access to a promising treatment option.

Scaling Options for Treatment Resistant Depression with Psilocybin-Assisted Therapy

With the expert team, purpose-built facilities, and proven care program already in place, Emyria is now fully equipped to support psilocybin-assisted therapy for treatment-resistant depression (TRD)—another major unmet need affecting at least 4% of the adult population [7].

Psilocybin-assisted therapy offers a potential option for patients who have not responded to conventional antidepressants or psychotherapy. By leveraging the same infrastructure, clinical expertise, and patient care model that has demonstrated success in MDMA-AT, Emyria is positioned to rapidly expand access to psilocybin treatment with the same rigorous standards of safety, efficacy, and real-world data collection.

This expansion further strengthens Emyria's leadership opportunity to deliver and evaluate new therapies for patients suffering from severe and persistent mental health conditions.

References:

1. Refer ASX Release 30th October 2023
2. Refer ASX release 02 September 2024
3. Marx BP, et al. Reliable and clinically significant change in the clinician-administered PTSD Scale for DSM-5 and PTSD Checklist for DSM-5 among male veterans. Psychol Assess. 2022 Feb;34(2):197-203.
4. https://innovation.ox.ac.uk/outcome-measures/recovering-quality-life-reqol-questionnaire/
5. 7%: https:// www.phoenixaustralia.org/ptsd-awareness-day - 11%: https://www.aihw.gov.au/reports/mental-health/stress-and-trauma
6. Previous studies estimate that the proportion of people with PTSD who experience a chronic and severe form is 50% (range 40–60%) [Koek RJ, et al]. Of this population, about 21.9% (range 12.5–41.5%) may be ineligible for MDMA-AT because of psychiatric and medical comorbidities such as any current substance use disorder, primary psychotic disorder, and bipolar disorder. Applying this calculus to Australian prevalences for PTSD suggests a potential patient population of ~800,000 adults who may be suitable for MDMA-AT. [For detailed analysis, see Avanceña, at al. The Costs and Health Benefits of Expanded Access to MDMA-assisted Therapy for Chronic and Severe PTSD in the USA: A Modeling Study. Clin Drug Investig 42, 243–252 (2022). https://doi.org/10.1007/s40261-022-01122-0]

7. https://www.sciencedirect.com/science/article/pii/S2772598724000230

Emyria's MDMA-AT Program

ITEM		DESCRIPTION
Program Title		An Evaluation of MDMA-AT for the Treatment of PTSD
Primary Endpoint(s)		Evaluate the safety and efficacy of up to three doses of MDMA in participants with PTSD.
Clinical Assessments		PTSD symptom severity by **PCL-5**: ("Post-Traumatic Stress Disorder Checklist for DSM-V") A 20-item self-report tool used to measure PTSD symptoms according to DSM-5 criteria. Quality of Life by **ReQoL**: ("Recovering quality of life") measures quality of life in individuals with mental health conditions, focusing on wellbeing, functioning, and recovery *Other clinical and safety assessments cover symptoms depression, disability, psychological distress and adverse events*
Development Phase		Real-World, open-label, no-control group
Treatment Method, Route, Frequency, Dose Levels, Expected **Duration**		A highly structured 6-16 week regimen, involving over 90 hours of therapy and specialist involvement. The program unfolds in distinct stages: thorough screening, preparation, and drug tapering (if required); followed by carefully supervised medication-assisted therapy sessions with multiple, intervening integration sessions. The average duration from initial screening to treatment conclusion for the current cohort was 106 days
Number of Subjects & Selection Criteria		8 patients have now reached 3 months post-treatment 24 currently in active treatment.
Locations		Emyria's Empax Centre in Perth Western Australia

This release has been approved by the Board of Emyria.

For further information, investment opportunities, or more about our approach to mental health treatment, please contact:

Greg Hutchinson
Chair
+61 (0) 8 6559 2800
ghutchinson@emyria.com

Emyria Limited develops and delivers new treatments for mental health and select neurological conditions through an integrated model of direct clinical services and drug development:

generates

informs

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 and psilocybin-assisted therapy for treatment-resistant depression.

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

Emyria's Pipeline: New psychedelic-assisted therapies and drug treatments for mental health and select neurological diseases.

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.

Risks associated with the use of MDMA, MDMA-inspired compounds and psilocybin

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. Adverse effects of psilocybin can include temporary increase in blood pressure and a raised heart rate. There may be some risk of psychosis in predisposed individuals. The effects of MDMA and psilocybin 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. The risk profile of the MDMA inspired compounds is currently unknown.

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, psilocybin or MDMA inspired compounds that the TGA has evaluated for quality, safety and efficacy.