emyria

Delivering & developing new treatments for mental health & neurological conditions

ASX Announcement | 02 Sept 2024

Emyria Announces Promising Interim Clinical Results for PTSD Program, Highlighting Significant Market Potential and Strategic Expansion Plans

HIGHLIGHTS

- Interim analysis of the first eight patients completing Emyria's MDMA-assisted therapy (MDMA-AT) program for Post-Traumatic Stress Disorder (PTSD) has demonstrated all patients achieved substantial improvement in PTSD symptoms, with a clinically and statistically significant average reduction of 33 points in PCL-5 scores.
- All patients reported substantial gains in quality of life, with a mean improvement of 22 points on the ReQoL scale, highlighting the broad impact of Emyria's MDMA-AT program beyond symptom relief.
- Emyria continues to evolve its leading care programs by actively collecting and applying Real-World Data, setting the standard for PTSD care and reinforcing its global leadership in developing promising new mental health treatments.
- Emyria plans to leverage existing revenues to fund the expansion of its programs and is actively engaging with private hospitals and third-party payers to broaden access and secure reimbursement.
- Findings to be presented this week by Emyria's Lead Psychiatrist, Dr Jon Laugharne, at the **WA Branch Conference of the Royal Australian and New Zealand College of Psychiatrists** Fri (6th Sep) & Sat (7th Sep)

Emyria Limited (ASX: EMD) ("Emyria", or the "Company") delivering and developing new treatments for mental health and select neurological conditions, is pleased to announce promising interim clinical results from analysis of its MDMA-assisted therapy (MDMA-AT) for Post-Traumatic Stress Disorder (PTSD) program which commenced in October 2023. [1]

Early findings are from an initial cohort of eight patients with moderate to severe PTSD symptoms (as measured using the PCL-5) and who were getting limited relief from standard treatment prior to enrollment. All eight patients completed Emyria's comprehensive program at Emyria's Empax Centre and demonstrated substantial improvement in patient outcomes at the end of their active treatment.

Clinically and statistically significant improvements were observed in PTSD symptoms and quality of life, as measured by PCL-5 and ReQoL assessments, respectively highlighting the program's potential to address significant unmet needs in PTSD care. An additional five patients are currently enrolled and undergoing treatment, with the program progressing towards its recruitment goal of 70 initial patients.

Significant PTSD Symptom Reduction

Emyria's MDMA-AT program has shown an average reduction of 33 points in PCL-5 scores—a critical measure of PTSD severity—demonstrating that patients experience significant symptom relief. Encouragingly, all participants achieved clinically meaningful improvements (a PCL-5 change > 12 points) [2], with many reaching PCL-5 scores below 30, a key threshold indicating substantial symptom reduction. Improvements were also statistically significant. A detailed program overview is provided below.

Mean PCL-5 Scores: Baseline vs Post-Treatment

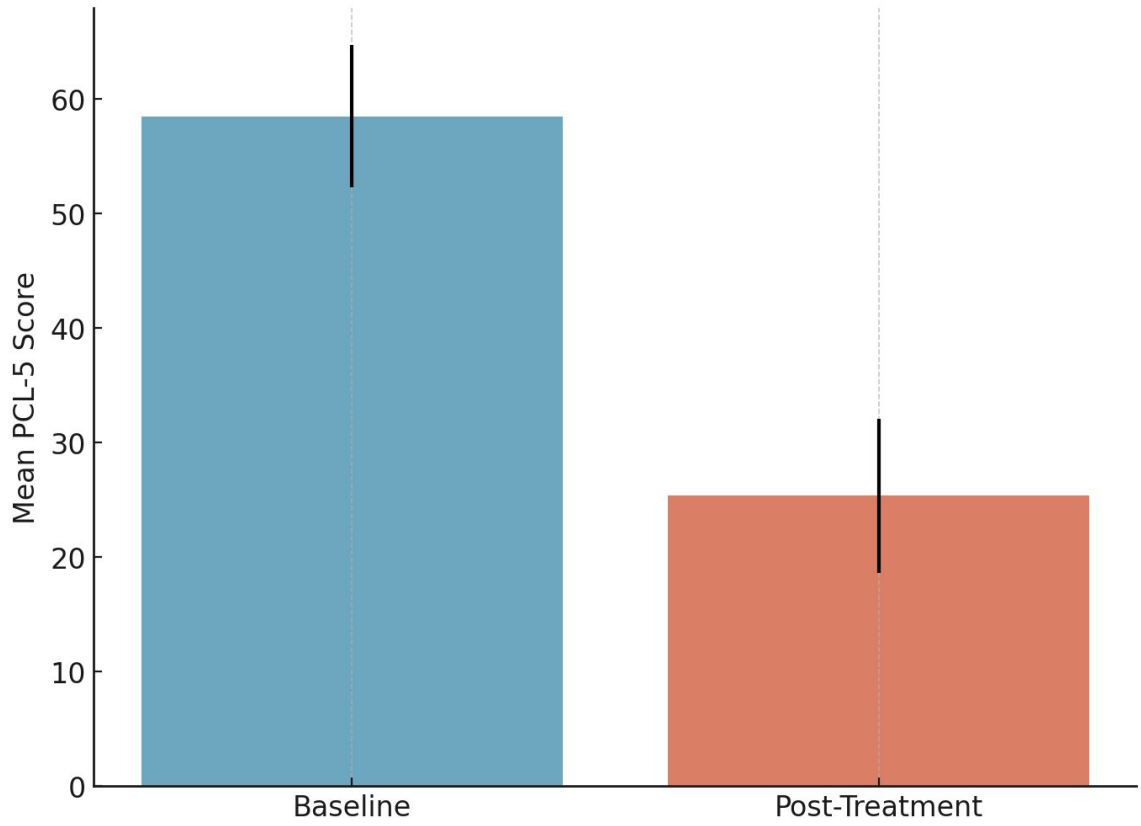

Figure 1: Mean Percentage Improvement in PCL-5 Scores

This chart illustrates the mean percentage improvement in PCL-5 scores among patients undergoing MDMA-assisted therapy (MDMA-AT) for PTSD comparing the assessment taken before treatment ("Baseline") to at least 1 month after the end of the program ("Post-treatment"). The significant reduction in PCL-5 scores demonstrates the effectiveness of Emyria's program in alleviating PTSD symptoms, highlighting its potential as a treatment option. 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).

- **Mean Change in PCL-5 Scores:** 33.1 points
- **95% Confidence Interval for Mean Change:** (20.96, 45.29) points
- **Paired t-test**: p-value = 0.0011 (statistically significant improvement)
- **Wilcoxon Signed-Rank Test:** p-value = 0.0078 (statistically significant improvement)
- **Patients Experiencing Clinically Significant Improvement:** All patients in this cohort achieved a clinically significant improvement (a reduction of 12 points or more in their PCL-5 scores).[1]

Significant Quality of Life Enhancements

Additionally, ReQoL quality of life measures improved by an average of 22 points, highlighting the broad impact of Emyria's MDMA-AT on patients' overall well-being.

Mean ReQoL Scores: Baseline vs Post-Treatment

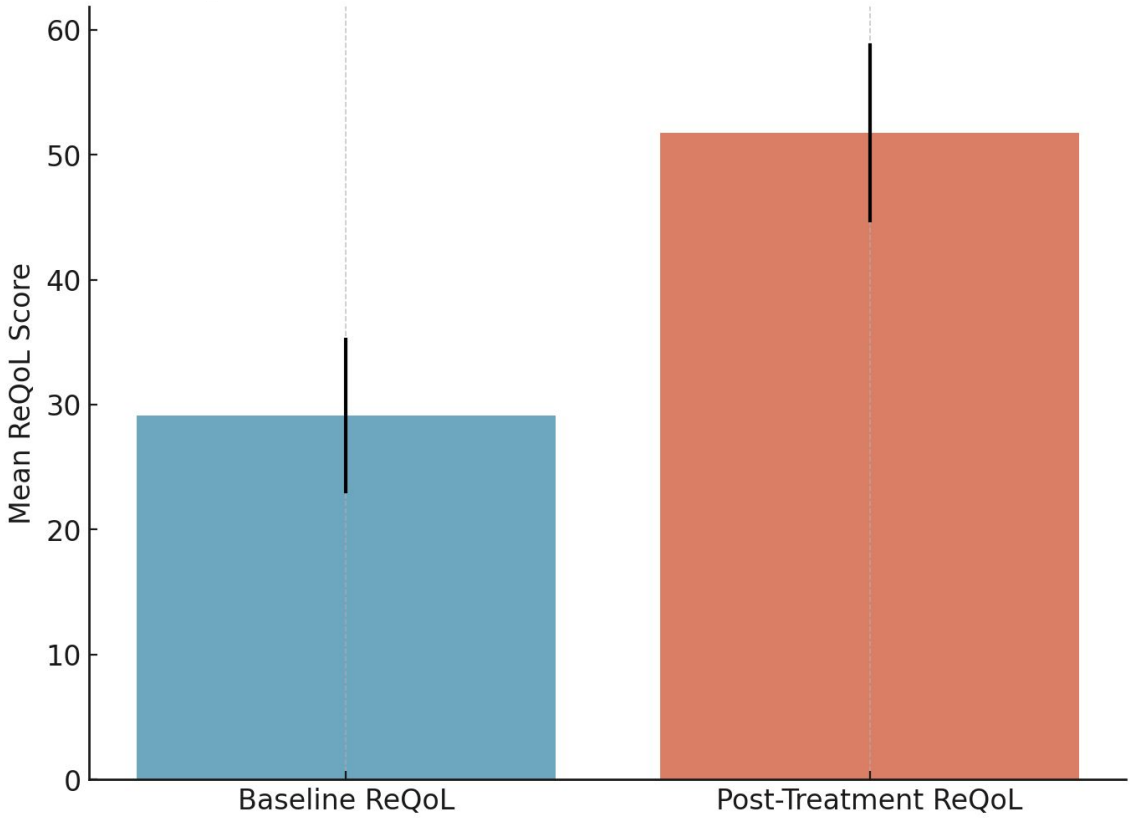

Figure 2: Mean Percentage Improvement in ReQoL Scores

This chart shows the mean percentage improvement in ReQoL scores from baseline to post-treatment for 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.

- **Mean Change in ReQoL Scores**: -22.6 points (indicating an improvement in quality of life)
- **95% Confidence Interval for Mean Change:** (-34.89, -10.36) points
- **Paired t-test:** p-value = 0.0086 (statistically significant improvement)
- **Wilcoxon Signed-Rank Test**: p-value = 0.0078 (statistically significant improvement)

Michael Winlo, CEO: *"These early Real-World results from our MDMA-Assisted Therapy program highlight the significant potential of this approach for PTSD care and provide an early indication of its effectiveness in real clinical settings beyond controlled trials. Emyria is uniquely positioned to lead the global development and refinement of this treatment as Australia is currently the only jurisdiction permitting these therapies under stringent oversight. We believe we have a substantial head start in gathering crucial Real-World Data and refining the approach to fully realise the potential of MDMA-AT thereby helping patients and also advancing the therapy's ongoing improvement."*

Program Structure

Emyria's MDMA-AT program is a rigorous 10-16 week regimen involving over 90 hours of therapy and specialist involvement. The program's structure includes thorough screening, preparation, and drug tapering if required, supervised medication-assisted therapy sessions, and comprehensive follow-up integration. On average, the length of treatment from screening to completion is 106 days, reflecting the program's commitment to providing structured and supportive care tailored to each patient's needs.

Initial Cohort Details

The interim results are based on data from an initial cohort of eight patients (six males and two females) with ages ranging from 27 to 62 years (mean 45 years) with baseline PCL-5 scores ranging from 47 to 82 and an average score of 68, indicating a high level of initial symptom severity. All patients (n=8) participating in the program successfully completed the full treatment cycle, which involved either two (n=2) or three (n=6) supervised dosing sessions of MDMA-AT. The number of supervised dosing sessions was determined by clinical evaluation taking into consideration symptom progression at regular clinical reviews. An additional five patients are nearing completion of active treatment with others in active screening. Emyria has an open enrolment target of 70 patients for this program.

Treatment Response According to PTSD Symptom Severity

Patients showed substantial improvements with an average 33% reduction in PTSD symptoms as measured by PCL-5 scores. Notably, all patients achieved at least a 20% reduction in symptoms, while 40% experienced a reduction of 50% or more, demonstrating the robust impact of Emyria's MDMA-AT program on severe PTSD. The variability in response ranged from mild improvements to reductions exceeding 50%, highlighting the individualised nature of therapy outcomes.

Treatment Safety

Adverse events were mild and transient, 1 in 4 patients experiencing either transient high blood pressure, nausea or jaw clenching. All side effects were self-limiting and effectively managed within the controlled clinical environment, underscoring the importance of specialist oversight.

Meaningful Implications for PTSD Patients

These results are particularly significant for the estimated 6-7% of adults suffering from PTSD [3], many of whom struggle with treatment resistance to conventional medications such antidepressants, or other 'gold-standard' approaches such as Cognitive Behavioral Therapy (CBT) or Prolonged Exposure (PE) therapy. Emyria's data suggests that MDMA-AT can offer a potentially more effective and enduring treatment option for patients who have not found relief through standard options, highlighting the potential of this approach for PTSD care.

Addressing a Large, Unmet Need in PTSD Care

With approximately 400,000 individuals in Australia who could benefit from MDMA-AT [4], the market opportunity is substantial. Emyria's program is strategically positioned to meet this demand. With a proven ability to deliver commercially viable and high-demand services, Emyria expects to see continued growth in activity and revenue throughout the remainder of the year.

Scalable Expansion Backed by Operational Readiness

Emyria's expansion strategy is fuelled by revenue from existing operations, allowing for growth without significant upfront capital. Recent operational advancements include the onboarding of seven experienced therapists and two medical practitioners trained in Emyria's unique care models. This expanded team, now numbering over 20 clinical professionals, is set to support rapid growth and meet increasing demand.

Emyria is actively negotiating site expansions and new care models with several private hospitals, and is poised to enhance its footprint on Australia's east coast through strategic recruitment of specialists. This positions Emyria to rapidly scale its unique programs and extend its impact across the nation.

Differentiating Through Data-Driven Care

Emyria operates as a unique learning health service, continuously gathering data to refine and enhance care models, thereby improving clinical outcomes. Emyria's unique multidisciplinary approach involving specialists and therapists provides a comprehensive, patient-centred and coordinated treatment journey, allowing for more effective PTSD care compared to fragmented traditional therapies.

Advancing Regulatory and Reimbursement Pathways

Australia remains the only jurisdiction globally with a legal access pathway for MDMA-AT [5] and Emyria is committed to maintaining compliance with stringent regulatory requirements. The Company is in advanced discussions with several major third-party payers regarding potential pilot programs anticipated to launch by year's end. These engagements reflect a broader effort to secure reimbursement, addressing the high costs of mental health care for patients and insurers and paving the way for broader adoption of promising new approaches.

Emyria's Long-term Vision and Strategic Goals

Emyria aims to become a global leader in the delivery and development of new treatments for mental health and select neurological conditions. The Company believes the future of mental health care will involve both new drug treatments and new models of supportive psychotherapy. Consequently, Emyria is advancing an ambitious innovation and IP pipeline in both domains. Under this model, the Company can uniquely deliver immediate patient benefits while also creating new IP for long-term value creation.

Investor Engagement and Upcoming Presentations

Emyria invites investors to learn more about these results and the Company's future plans:

- **WA Branch Conference of the Royal Australian and New Zealand College of Psychiatrists:** September 6th - 7th. Dr. Jon Laugharne, Emyria's lead psychiatrist, will present a summary of these early results.
- **Stock Soiree:** Wednesday, September 4th. Register: holly @ stocksoiree . com . au
- **ShareCafe's "Hidden Gems" Webinar:** Friday, September 6th (registration details to follow).

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
Treatment Method, Route, Frequency, Dose Levels, Expected	A highly structured 10-16 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.
Duration	The average duration from initial screening to treatment conclusion for the current cohort was 106 days\
Number of Subjects & Selection Criteria	8 patients in follow-up phase + 5 patients in active treatment
Locations	Emyria's Empax Centre in Perth Western Australia

References:

1. Refer ASX Release 30th October 2023
2. 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. doi: 10.1037/pas0001098.
3. https:// www . phoenixaustralia . org / ptsd-awareness-day
4. 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 ~400,000 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]
5. https://www.tga.gov.au/news/media-releases/change-classification-psilocybin-and-mdma-enable-prescribing-authorised-psychiatrists

This release has been approved by the Board of Emyria.

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Emyria Limited develops and delivers new treatments for mental health and select neurological conditions through 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: 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

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 of 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.