

Emyria (ASX:EMD) Investment Report

Investing in the Future of Mental Health: Emyria's Growth

Overview: Emyria Limited (ASX: EMD) is an Australian healthcare company focused on developing and delivering innovative treatments for unmet mental health and neurological conditions. It is the only ASX company specializing in the delivery of psychedelic-assisted therapies while also developing novel prescription-based treatments for disorders like PTSD, Parkinson's disease, chronic pain, and anxiety. Founded in 2018, Emyria operates with a team of 11–50 employees based in Leederville, Western Australia.

Key Achievements:

- Strategic Collaborations:** Partnered with the University of Western Australia to develop and commercialize novel MDMA-inspired therapies targeting PTSD and Parkinson's disease. Emyria is also working closely with the National Institutes of Health (NIH) in the USA on both of its drug development programs.
- Therapeutic Development:** Advanced key projects, including EMD-MX1 (MDMA analogue for PTSD) and EMD-RX7/9 (CBD capsules for pain and anxiety).
- Innovative Trials:** Launched MDMA-assisted therapy trials for first responders with PTSD, showcasing a tailored approach to a high-need demographic.
- Regulatory Advantages:** First-mover advantage and positioned to benefit from shifts in the regulatory landscape, especially in markets like the U.S. and Australia, which are increasingly supportive of psychedelic-assisted therapies and years head of other markets like the US.

Market Dynamics: The global market for PTSD treatment is expected to grow from \$13.2 billion in 2023 to \$19.4 billion by 2032, with Emyria targeting a significant share through its innovative approaches. Australia's mental health market, valued at \$564.2 million in 2024, highlights strong demand for cutting-edge treatments like those developed by Emyria. The Company is a global leader in the delivery of psychedelic-assisted therapies - an area attracting significant investment interest.

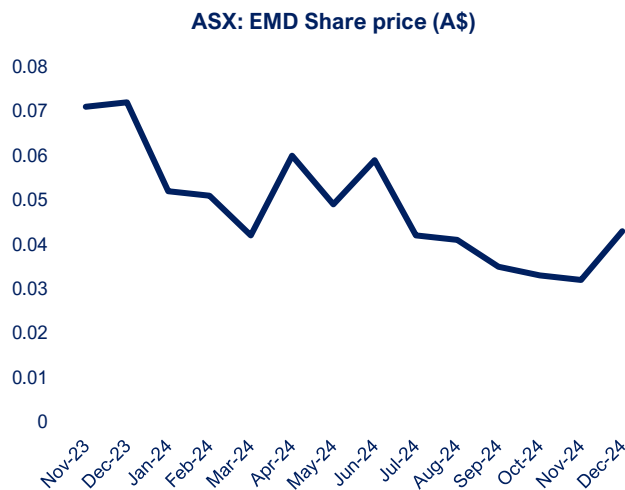
Recent Funding Success: Emyria Limited raised AU\$2.525 million in cash to the cash balance through a successful capital raise to support the expansion of its mental health initiatives, including advanced care programs for treatment-resistant depression. The placement involved the issuance of approximately 72.14 million shares at AU\$0.035 each, representing a discount to market price. Chairman Greg Hutchinson contributed AU\$1 million, with the capital raise divided into two tranches, the second of which is subject to shareholder approval in February 2025. Led by 62 Capital Pty Ltd, which received part of its fee in shares, this funding demonstrates strategic investor confidence and positions Emyria to secure significant third-party backing for its innovative care solutions.

Outlook: Emyria's innovative therapies, strategic partnerships, and focus on under-addressed mental health conditions position the company as a leader in the evolving mental health and PTSD treatment space. With supportive market conditions and growing awareness of psychedelic therapies, Emyria aims to drive meaningful advancements and solidify its market position in the coming years.

Share Price: 0.0430

ASX: EMD
Sector: Healthcare and Pharma
09 December 2024

Metrics	Value
Valuation Measures	
Market Cap	AUD 21.03M
Enterprise Value	AUD 17.87M
Share Information	
Shares Outstanding	489.16M
52 week high/low (A\$)	\$0.0760 / \$0.0265
% Held by Insiders	30.21%



Source: Yahoo Finance

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Mental Health: The Leading Health Concern in 2024

In 2024, a global survey spanning 31 countries found that **45% of respondents** cited **mental health** as the most critical health issue facing their nation. This figure exceeds the concerns surrounding **cancer (38%)**, **stress (31%)**, and **obesity (26%)**, highlighting the increasing recognition of mental health as a significant global health challenge. The heightened awareness of mental health issues can largely be attributed to the lasting effects of the **COVID-19 pandemic**, which played a pivotal role in emphasizing the importance of mental well-being worldwide.

The pandemic exacerbated mental health conditions, particularly **anxiety** and **depression**, as people faced **isolation**, **stress**, and **uncertainty**. As lockdowns and social distancing measures were implemented to curb the spread of the virus, feelings of **hopelessness** and **mental strain** surged, affecting millions of people globally. While vaccines and improved healthcare responses have mitigated the immediate effects of the pandemic, **11% of respondents** still identified **COVID-19** as a leading health issue in 2024, indicating the long-term mental health impact of the pandemic.

Mental Health Statistics and Global Impact

The two most prevalent mental health conditions worldwide are **anxiety disorders** and **depression**.

- **Anxiety disorders** affect **4.4%** of the global population, with many individuals experiencing heightened anxiety due to the pandemic's uncertainty.
- **Depression** impacts **4%** of people globally, with **females** experiencing higher rates (**4.3%**) compared to **males (2.9%)**.
- **Suicide** rates, however, are notably higher among men, despite depression being more common in women. This gender disparity in mental health underscores the importance of targeted support services for different groups.

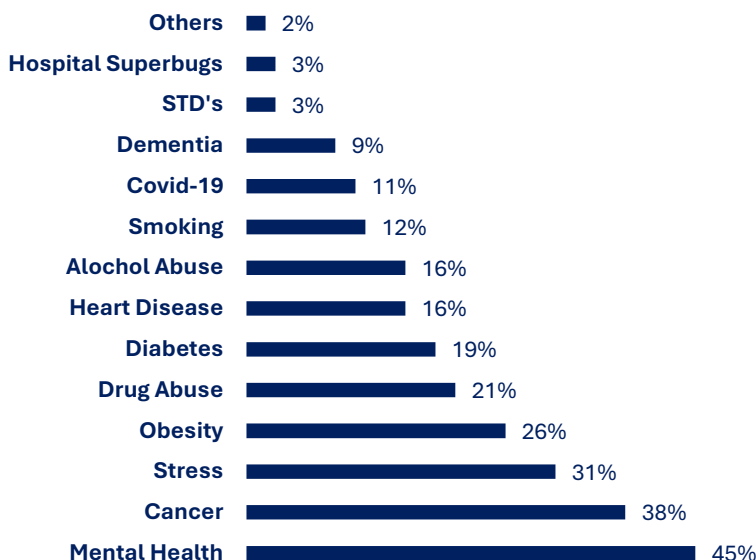
Shifting Focus and Future Implications

The pandemic's spotlight on mental health has had some positive effects, particularly in reducing the **stigma** surrounding mental health issues. As mental health has become more publicly acknowledged as a critical health concern, there has been a growing recognition of the need for improved access to **mental health care**. This shift in public attitudes is expected to lead to long-term improvements in the availability of mental health services, as well as greater societal support for those affected by mental health conditions.

The increased awareness of mental health challenges, combined with changes in attitudes towards seeking help, could significantly alter the landscape of mental health care systems globally. **Early intervention**, **preventive care**, and **access to treatment** are likely to become more central to healthcare policies. With **mental health issues** now identified as one of the biggest health challenges, countries may prioritize funding for mental health services, leading to better outcomes for millions worldwide.

In the coming years, this shift in focus could lead to a world where mental health is treated with the same level of urgency and importance as physical health, reducing the burden on individuals and healthcare systems alike. As societies continue to adapt to the evolving needs of their populations, a more robust, comprehensive approach to mental health care may become a global priority.

Major Health Concerns in 2024

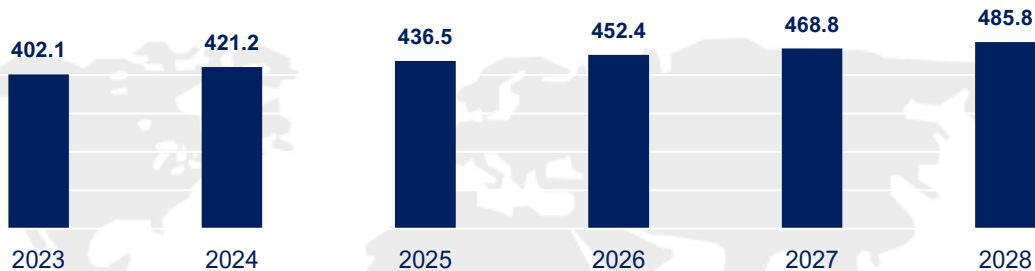


Source: Statista

Mental Health Market Analysis: Global

The global mental health market, valued at \$402.13 billion in 2023, is projected to grow to **\$421.24 billion in 2024, with a CAGR of 4.8%**. By 2028, it is expected to reach \$485.78 billion at a slower CAGR of 3.6%. This steady growth reflects increased awareness, government support, and the expansion of telepsychiatry and early intervention initiatives.

Global Mental Health Market (USD Billion)



Source: Research and Markets

Key Growth Drivers

- **Technological Integration and Telepsychiatry:** Digital mental health platforms and AI-driven services have made mental health care more accessible, especially during global health crises. Innovations such as mobile apps, virtual therapy, and wearable devices are reshaping service delivery.
- **Public-Private Partnerships and Employer Initiatives:** Collaborative efforts between governments and private sectors, alongside workplace mental health programs, are creating more comprehensive support systems.
- **Cultural Competency and Diversity:** Efforts to provide culturally sensitive care are improving service reach and effectiveness.

MDMA as a Market Driver

MDMA-assisted therapy, particularly for PTSD, is gaining traction as a groundbreaking treatment. Clinical trials have demonstrated significant efficacy, with 71.2% of participants no longer meeting PTSD criteria after MDMA therapy compared to 47.6% with traditional methods. MDMA is likely to secure FDA approval, marking a shift in how mental health disorders are treated and potentially expanding the market for psychedelic-assisted therapies.

Challenges: Cost of Treatment

High treatment costs pose a barrier to market growth. Rising healthcare expenses, driven by complex therapies and insurance challenges, limit access. Surveys indicate that managing these costs is a priority for employers, with mental health expenses projected to rise by 6.4% in 2024.

Local Special Circumstances

In developed regions, the mental health market benefits from established infrastructure and greater societal acceptance. Developing nations face challenges such as limited resources and stigma, although awareness campaigns and funding initiatives are driving improvement.

Underlying Macroeconomic Factors

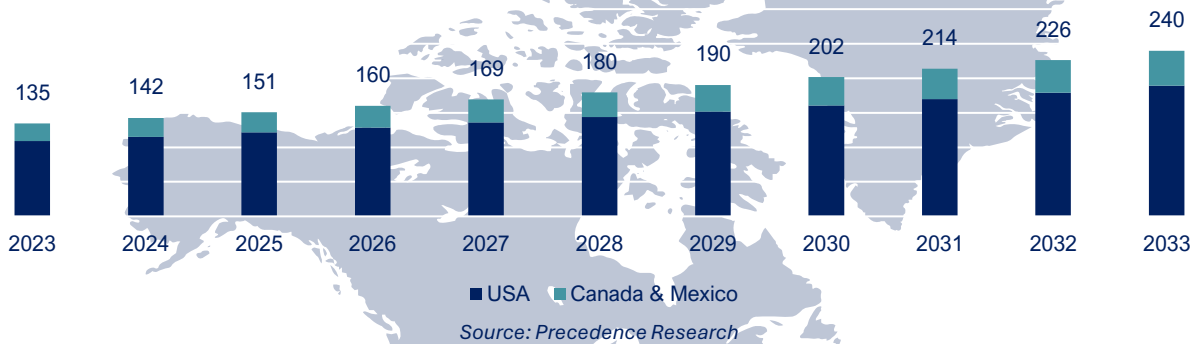
Urbanization and the lasting psychological impacts of the COVID-19 pandemic are driving demand for mental health services. Government policies and supportive regulations in many countries are improving access, though disparities remain evident between regions.

Globally, the mental health market is growing due to increasing awareness, technological advancements, and evolving societal attitudes. North America leads in per-person spending and innovation, driven by robust infrastructure and demand for teletherapy and workplace programs. Australia, though smaller in scale, shows notable growth fueled by government support, high prevalence rates, and the adoption of digital and holistic mental health solutions. Each region reflects unique dynamics that together paint a promising picture for the future of the mental

Mental Health Market Analysis: North America

The North America mental health market is set to experience significant expansion, with a projected value of **USD 239.58 billion by 2033**, growing at a **CAGR of 5.90%** from 2024. The U.S. holds a dominant position, contributing **80.96% of the market share** in 2023. This growth is fueled by increasing awareness, government initiatives, and advancements in evidence-based treatment approaches.

North America Mental Health Market (USD Billion)



Disorder Analysis: Focus on Anxiety and Depression

Anxiety disorders dominated the market with a **47.41% share** in 2023, driven by increased awareness and advancements in treatment modalities like cognitive-behavioral therapy (CBT) and selective serotonin reuptake inhibitors (SSRIs). The rising prevalence of **depression** also contributes significantly to market growth, supported by telehealth initiatives that enhance accessibility and engagement.

End-User Preferences: Outpatient Clinics Lead

Outpatient clinics accounted for **36.85%** of the market share in 2023. These facilities offer convenient access to services and play a critical role in early intervention and ongoing support. The **homecare segment** is the fastest-growing, reflecting a broader shift toward patient-centric care models and regulatory support for home-based behavioral health services.

Regional Insights: U.S. and Canada's Impact

The **United States** leads the market due to supportive policies like Medicaid expansion and mental health parity laws, which have increased access to services. Government funding initiatives, including a **\$36.9 million** allocation in 2024, further support the market's growth. In **Canada**, public health campaigns and increased funding are driving demand, despite challenges such as resource shortages and long wait times.

Recent Innovations and Developments

Key developments include the approval of community-based **mobile crisis response teams** in New Mexico and initiatives by organizations like Tennis Canada to promote mental health in sports. These efforts highlight a growing focus on mental wellness and innovative service delivery models.

Local Special Circumstances in North America

The region's predominantly private healthcare system poses affordability challenges, with out-of-pocket expenses creating barriers for some populations. North America's strong research infrastructure fosters innovation in treatment modalities, while increasing public and governmental focus on mental health is addressing stigma and encouraging people to seek care.

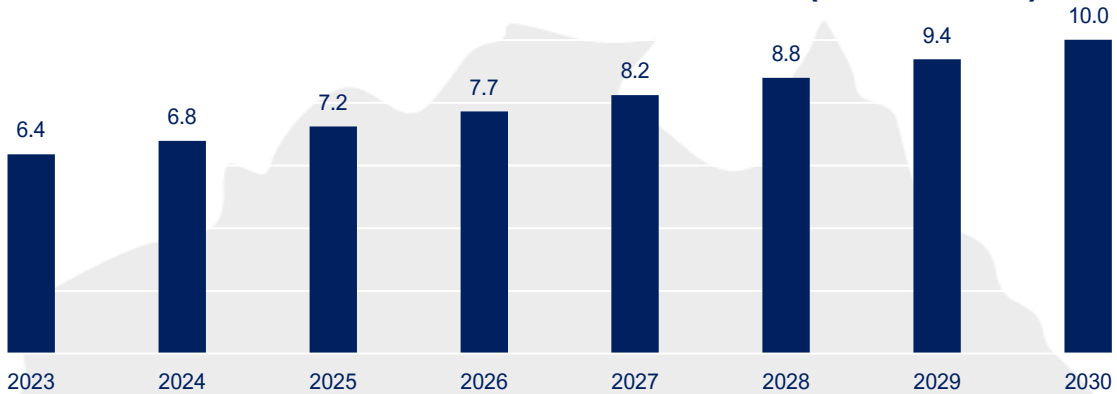
Underlying Macroeconomic Factors in North America

The robust North American economy supports significant investment in healthcare services, including mental health. Rising healthcare costs are spurring innovation in **cost-effective solutions** like digital platforms and telehealth. Moreover, the aging population is contributing to increased demand for mental health services, particularly for disorders like depression and anxiety.

Behavioral Rehabilitation Market Analysis: Australia

The **Australia behavioral rehabilitation market** saw a revenue of **USD 6,356.1 million** in 2023, with expectations to grow to **USD 10,009.3 million by 2030**, representing a **CAGR of 6.7%** from 2024 to 2030. This growth is primarily driven by the increasing prevalence of mental health disorders and greater access to behavioral health services.

Australia Behavioral Rehabilitation Market (USD Billions)



Source: Grand View Research, Australian Bureau of Statistics

Key Market Insights

Outpatient Care Dominance: In 2023, outpatient care was the largest revenue-generating segment in the Australian behavioral rehabilitation market. This setting is also expected to see the **fastest growth** during the forecast period, as outpatient services offer flexible, cost-effective solutions for individuals with mental health issues.

Mental Health Prevalence: Around **42.9%** of individuals aged **16-85 years** in Australia have experienced a mental disorder at some point in their lives. Of these, **21.5%** had a mental disorder in the past 12 months, with **anxiety disorders** being the most common (affecting **17.2%** of the population).

Age Group Vulnerabilities: The **16-24 years** age group shows a notably high prevalence of mental health issues, with **38.8%** reporting a 12-month mental disorder, highlighting the growing need for targeted rehabilitation services.

Population Breakdown: Out of the total population of **19.83 million** individuals aged **16-85 years**:

- **42.9%** have experienced a mental disorder in their lifetime.
- Of these, **21.5%** had a mental disorder in the past 12 months, creating a significant demand for rehabilitation and treatment services.

Local Special Circumstances

Australia's mental health landscape is influenced by a high prevalence of disorders, with **one in five Australians** experiencing mental health issues annually. The government's prioritization of mental health has led to significant investments in public health initiatives, such as the establishment of the **National Mental Health Commission** and various funding programs. This supportive environment has accelerated the adoption of **digital health solutions** and improved access to services.

Underlying Macroeconomic Factors

Australia's **strong and stable economy** and aging population are major drivers of the mental health market. The aging demographic increases the demand for mental health services, as older adults are more likely to experience related issues. Additionally, societal attitudes toward mental health are evolving, fostering greater acceptance and demand for care. Government policies, such as expanded insurance coverage for mental health services, are also enhancing accessibility and affordability.

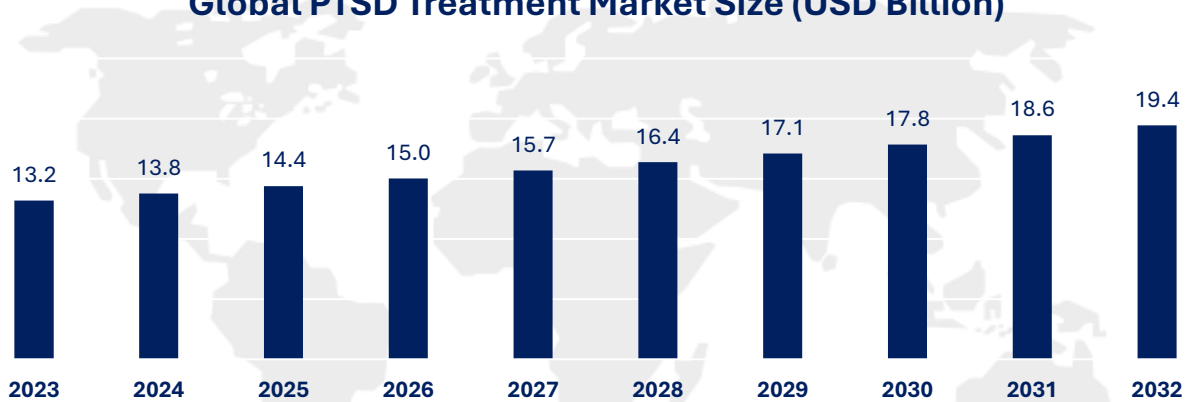
PTSD Treatment Market Analysis: Global

The **global PTSD treatment market** is expanding rapidly, projected to grow from **USD 13.2 billion in 2023** to **USD 19.4 billion by 2032**, at a **CAGR of 4.4%**. This growth is fueled by increasing awareness, better diagnostic capabilities, and the growing acceptance of alternative treatments, including **psychedelic-assisted therapies**.

In **2023**, **adults** made up the largest segment of the market, accounting for **57%** of total market share, followed by **geriatrics** at **33.5%** and **pediatrics** at **9.5%**. Among treatments, **antidepressants** led the revenue generation with **USD 6.5 billion**, highlighting their central role in current PTSD management strategies. **Hospital pharmacies** were the primary distribution channel, and this segment is expected to reach **USD 10.6 billion by 2032**, reflecting the importance of institutional settings in treatment delivery.

Emyria's focus on developing **MDMA-assisted therapy** for PTSD and **psilocybin-assisted therapy** for **treatment-resistant depression** aligns with the growing potential for **psychedelic-assisted therapies**. As these therapies gain acceptance in mainstream care, they present new opportunities for improving patient outcomes, driving further market growth, and offering significant growth prospects for companies like **Emyria**. However, as with any emerging therapeutic strategy, **financial challenges** linked to **R&D investments** and **administrative expenses** will require careful strategic planning to ensure sustained progress.

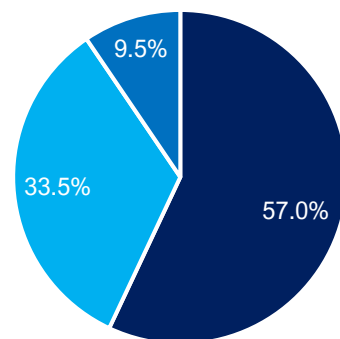
Global PTSD Treatment Market Size (USD Billion)



Source: GM Insights, Market Research Future

PTSD Treatment Market - By Age Group

The need for effective PTSD treatments is underscored by the **global prevalence** of PTSD, with **1 in 13 people** expected to develop the condition during their lifetime. Women are disproportionately affected, with an estimated **9.7%** of women experiencing PTSD compared to **3.6%** of men. In **Australia**, **12%** of individuals experience PTSD over their lifetime, and in the **U.S.**, **70% of adults** are exposed to trauma, with **20%** developing PTSD. Furthermore, the demand for PTSD treatments is intensified by global crises like the **COVID-19 pandemic** and the **Russia-Ukrainian War**, which have exacerbated trauma-related conditions. The growing global demand for innovative PTSD treatments, such as those developed by **Emyria**, positions the company to contribute significantly to meeting these needs, potentially transforming the treatment landscape and improving outcomes for those affected by PTSD.



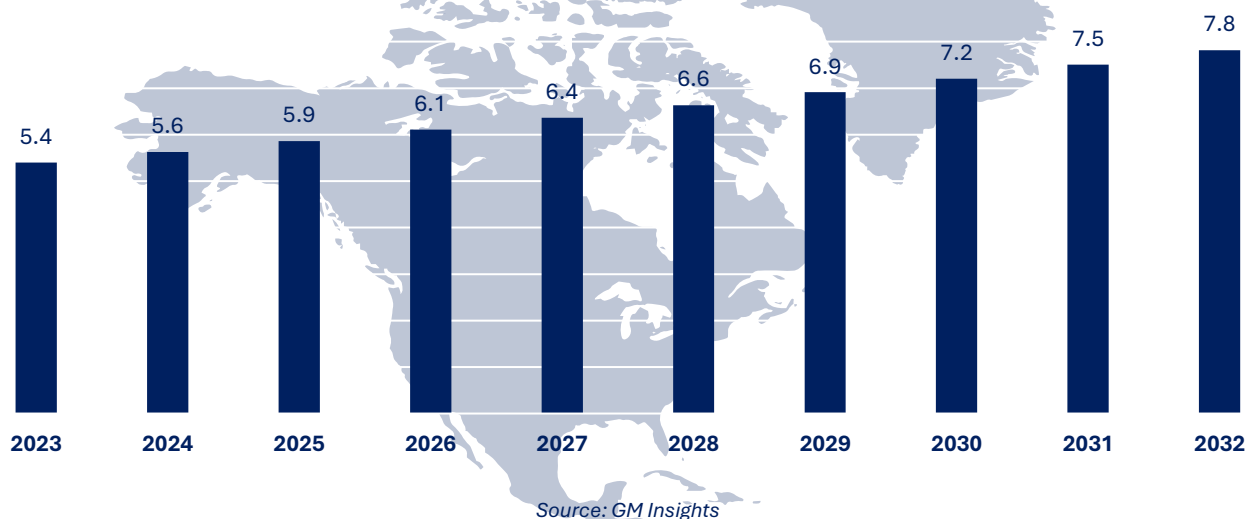
■ Adult ■ Geriatrics ■ Pediatrics

Source: GM Insights, Market Research Future

PTSD Treatment Market Analysis: North America

The **North American PTSD treatment market**, accounting for **43% of the global market share in 2023**, is a key region for the growth of PTSD therapies. Valued at **USD 5.4 billion in 2023**, the market is projected to grow at a **CAGR of 4.20%** between 2024 and 2032, reaching **USD 7.8 billion by 2032**.

North America PTSD Treatment Market Size (USD Billion)



United States

In the U.S., approximately **8 million adults** are affected by PTSD annually, with prevalence particularly high among **veterans, first responders, and survivors of violence**. The growth of the PTSD treatment market is supported by **government funding**, rising public awareness, and an expanding workforce of mental health professionals. Initiatives to integrate innovative therapies and improve access to care further bolster the market.

Canada

PTSD impacts **10% of Canadians** during their lifetime. Market growth is driven by increased **government funding, mental health initiatives**, and the adoption of **innovative therapies** such as virtual reality treatments. These advancements reflect Canada's proactive approach to addressing mental health challenges and expanding treatment options.

Market Dynamics

The rising prevalence of PTSD in North America, coupled with advancements in treatment methods and increased public and private sector investments, positions the region as a leader in the PTSD treatment landscape. The focus on **early intervention, technological innovation**, and enhanced accessibility continues to shape the market's trajectory.

Recent Developments

- **April 2024:** Otsuka Pharmaceutical Co. and H. Lundbeck A/S announced FDA acceptance of a **supplemental application for Brexpiprazole combined with sertraline** for PTSD treatment.
- **August 2024:** Lykos Therapeutics FDA registration application for **MDMA capsules** designed for use alongside psychotherapy, was rejected, Lykos are required to perform another Phase 3 trial highlighting the significant head-start provided by the Australian regulatory environment.

With a growing focus on mental health awareness, innovative therapies, and government support, the North American PTSD treatment market is poised for sustained growth. The region's significant share of the global market underscores its pivotal role in advancing treatments and addressing the rising demand for PTSD care.

US Election Effect: MDMA & Psilocybin assisted Therapies

Following the U.S. elections, Donald Trump appointed **Robert F. Kennedy Jr. as Secretary of HHS**, signaling a potential shift in drug policy reform. Kennedy, known for questioning conventional medical practices, has emphasized the need for innovative approaches to treating mental health disorders, particularly in veterans. **Martin Makary, nominated as FDA Commissioner**, has also expressed interest in re-evaluating psychedelic therapies like MDMA and psilocybin. Both figures are vocal advocates for expanding access to alternative therapies, including MDMA and psilocybin.

Kennedy has consistently emphasized the therapeutic potential of psychedelics, particularly for veterans suffering from PTSD. He has criticized the FDA for its stringent regulations, describing the agency's actions as "aggressive suppression" of promising treatments. Kennedy has vowed to leverage his role at HHS to promote access to MDMA and other psychedelics, aligning himself with veterans' groups and advocates pushing for reforms



Source: CNN News



Source: Twitter

Critique of FDA's Actions: Kennedy has criticized the FDA for what he describes as "aggressive suppression" of psychedelics, including MDMA. He believes that the agency's rejection of MDMA-assisted therapy for PTSD reflects a broader issue of regulatory resistance to innovative treatments that could benefit patients suffering from mental health disorders

Advocacy for Psychedelic Therapies: He has highlighted the therapeutic potential of psychedelics, arguing that they should be more accessible to those in need. Kennedy views MDMA as a promising option for individuals with PTSD, emphasizing the importance of exploring all avenues for effective treatment


Vision for Drug Policy Reform: In his proposed role within the Trump administration, Kennedy aims to reshape drug policy to facilitate access to psychedelic treatments. He has indicated that he would leverage his position at the Department of Health and Human Services (HHS) to promote reforms that would allow for the use of MDMA and other psychedelics in therapeutic settings

Support from Veterans and Advocates: Kennedy has aligned himself with veterans' groups and advocates who have been pushing for the approval of MDMA-assisted therapy, recognizing the significant mental health challenges faced by veterans and the potential benefits of such treatments.

Global Influence : MDMA & Psilocybin assisted Therapies

International precedents set by countries like Canada and Australia are influencing U.S. policy considerations:

- **Canada's Cannabis Legalization:** As the first G7 nation to legalize recreational cannabis, Canada has established a comprehensive medical cannabis framework. This framework facilitated the approval of treatments like Sativex for multiple sclerosis, demonstrating a progressive stance on alternative therapies.
- **Australia's Approval of MDMA and Psilocybin:** In 2023, Australia became one of the first countries to officially recognize MDMA and psilocybin as medicines, approving their use for treating PTSD and treatment-resistant depression. This decision reflects a growing acceptance of psychedelic-assisted therapies in mainstream medical practice and provides Emyria with a significant, hard-to-catch, head start in this market.



With the combined efforts of RFK Jr. and Makary, the U.S. is poised to accelerate the acceptance of psychedelic-assisted therapies. Their shared commitment to reform and patient-focused innovation indicates that FDA approval of MDMA and psilocybin for therapeutic use may soon become a reality, driven by a renewed emphasis on scientific integrity and public trust.

About: Emyria Limited

Overview

Emyria Limited is an Australian healthcare company delivering and developing innovative treatments for unmet mental health and neurological needs. It specializes in MDMA-inspired medicines and CBD-based prescription therapies for conditions like PTSD, Parkinson's disease, complex pain, and anxiety. Formerly known as **Emerald Clinics Limited**; renamed to Emyria Limited in September 2020.

Key Business Areas

- **Drug Development:**
 - **EMD-MX1:** Faster-acting MDMA analogue for PTSD with reduced side effects.
 - **EMD-MX2:** Adjunct treatment for Parkinson's disease.
 - **EMD-MX3:** Neurological applications in early research.
 - **EMD-RX7/9:** CBD capsules under preclinical trials for pain and anxiety.
- **Collaborations:** Partnered with the **University of Western Australia** to advance MDMA analogue drug development programs targeting mental health and neurodegenerative diseases.
- **Clinical Services:**
 - **First service** in Australia to commence MDMA-Assisted Therapy
 - Over **20 trained clinicians and specialists**
 - Working with **major health payers** on funding pathways
 - **Successfully treated nearly 20 patients** and generating strong revenues and now expanding programs to include psilocybin-assisted therapy

Key Details

- **Founder:** Stewart Washer and Matt Callahan
- **Headquarters:** Leederville, Western Australia
- **Year Founded:** 2018
- **Employee Size:** 11–50
- **Revenue (FY 2024):** AUD 2.2 million
- **Number of Facilities:** Operates multiple clinical service subsidiaries, including **The Pax Centre** for psychological trauma care and a specialist treatment centre – **Empax Centre** – dedicated to medication-assisted therapies with a focus on scalability.

Recent Developments

- **MDMA Therapy Trials for First Responders:** Emyria is conducting specialized MDMA-assisted therapy trials targeting first responders with treatment-resistant PTSD. This initiative, funded by Reach Wellness, involves up to 50 participants undergoing three eight-hour dosing sessions at the Pax Centre in Perth. Two therapists will facilitate each session, reflecting an innovative approach to addressing the unique mental health challenges faced by first responders. *(Source: Sharecafe, ABC)*
- **Capital Raising:** Emyria Limited raised AU\$2.525 million through a capital placement at AU\$0.035 per share, with Chairman Greg Hutchinson contributing AU\$1 million. The funds will support the expansion of mental health programs, including those at the Empax Centre, reflecting strong investor confidence and strategic growth in Emyria's treatment offerings
- **Partnership with the University of Western Australia (UWA):** Emyria has secured an exclusive licensing agreement with UWA to commercialize new serotonin-releasing agents aimed at treating mental health and neurological conditions. This collaboration highlights Emyria's commitment to advancing innovative mental health treatments, including those involving MDMA. *(Source: Investing News)*
- **Emyria Secures Ethics Approval for Psilocybin-Assisted Therapy:** Emyria Ltd has launched a psilocybin-assisted therapy program targeting treatment-resistant depression and secured ethics approval from the ACT Health Ethics Committee. With TGA approval expected soon, the company will offer both psilocybin and MDMA therapies, expanding care for complex mental health needs.
- **Partnering with Private Health Funds to Enhance Access to Innovative Therapies:** Emyria is partnering with major private health funds to develop funding pathways, making its psilocybin-assisted therapy for treatment-resistant depression more affordable and accessible to patients



Emyria's MDMA-Assisted Therapy

Emyria Limited (ASX: EMD) is a clinical services and drug development company that is pioneering the use of MDMA-assisted therapy (MDMA-AT) for PTSD treatment, particularly in cases that have proven resistant to conventional therapies. This approach leverages MDMA's unique effects to enhance therapeutic outcomes, providing an alternative to traditional pharmacological treatments. Emyria's primary focus is on developing and validating MDMA-AT through a clinical trial framework, ensuring its effectiveness in treating complex trauma.

In July 2023, the Australian Therapeutic Goods Administration (TGA) made a groundbreaking decision by descheduling MDMA, which allowed Emyria to initiate its EMDMA-001 trial and commence direct treatment for full fee-paying patients. This move represents a significant shift in the regulatory landscape, opening the door for further psychedelic therapies in the country. Emyria is not only testing MDMA-AT's clinical efficacy in Real-World contexts but also working to integrate it into broader healthcare systems by considering cost-effectiveness and quality-of-life metrics.

Clinical Trial and Safety Protocols

The EMDMA-001 trial is pivotal in assessing the safety and efficacy of MDMA-AT. Early results from similar studies conducted by organizations like MAPS (Multidisciplinary Association for Psychedelic Studies) have been promising, showing that approximately 70% of participants no longer met the criteria for PTSD after three MDMA-assisted sessions. This compares favorably to a placebo group where only 48% showed similar improvements. However, the therapy is not without its challenges, as MDMA can cause side effects like increased heart rate, anxiety, and jaw clenching. To mitigate these risks, Emyria has implemented rigorous safety protocols, including close monitoring of participants throughout the sessions. They also exclude individuals with pre-existing cardiovascular or psychotic conditions to minimize the risk of adverse events.

Expanding Access and Real-World Application

Beyond clinical trials, Emyria is developing real-world applications for MDMA-AT. They have introduced the Authorised Prescriber (AP) program, which enables private clinics to offer MDMA-assisted therapy to patients, bypassing traditional academic trial settings. This strategy is designed to expand access to psychedelic-assisted therapies, creating a more sustainable and scalable model for treatment. The acquisition of the Pax Centre, a clinical service specializing in trauma care, enhances Emyria's capacity to offer these services, further accelerating patient recruitment for ongoing trials.

Moreover, the acquisition of the Pax Centre signifies a broader strategy to position Emyria as a global leader in psychedelic-assisted therapy. This center will serve as a hub for innovative mental health treatments, including MDMA-AT, and supports Emyria's vision of establishing a Centre of Excellence for psychedelic therapies. By integrating the Pax Centre's capabilities with its existing clinics, Emyria is poised to significantly enhance its clinical trial and patient recruitment processes, helping to advance its research on MDMA-AT and, Emyria is establishing a strategy for rapid growth through a proven acquisition model with operational overlay.

Advancements in MDMA Analogues

Emyria is also exploring novel MDMA analogues to improve the safety, efficacy & patient reach of MDMA-assisted therapies. These new compounds are designed to have faster onset times and reduced side effects, which could make the treatment more accessible and easier to tolerate for patients. This ongoing research is critical as it could lead to more refined therapies with broader applications in treating PTSD and potentially other conditions like anxiety and depression.

Strategic Investments and Growth

Emyria recently completed a successful AU\$2.525 million capital raise, which will be used to accelerate its mental health services, including treatment-resistant depression programs at the Empax Centre. This funding is a key enabler for Emyria to continue expanding its footprint in the mental health sector, particularly in psychedelic-assisted therapy. The investment reflects growing confidence from professional investors in Emyria's approach, and it will help ensure the sustainability of its programs.

Comparing Emyria's EMDMA-001 and Lyko's MAPS Trials: Key Differences and Impact

1. Trial Design and Objectives

- **EMDMA-001 Trial (Emyria):** The EMDMA-001 trial by Emyria is designed to assess MDMA-assisted therapy for treatment-resistant mental health disorders, particularly PTSD and depression, under real-world clinical conditions. This trial is not confined to the controlled settings typically seen in early-phase research but instead aims to reflect the complexities of regular healthcare environments. By working with established mental health professionals and collecting real-world data, Emyria can refine and optimize its therapeutic protocols continuously. This data not only informs clinical practice but also feeds into the creation of **intellectual property (IP)**, setting the stage for scalable treatment models that can be supported across a network of clinics linked to Emyria's network.
- **MAPS Trial (Lykos):** The MAPS Phase 3 clinical trials focus on MDMA-assisted therapy for PTSD and are more structured in terms of regulatory and research standards. They are part of the FDA's Breakthrough Therapy designation, indicating the potential for rapid approval based on the promising clinical outcomes observed. These trials focus heavily on the efficacy and safety of MDMA therapy under controlled conditions, using well-established metrics for symptom reduction (e.g., PTSD Diagnostic Scale, CAPS-5) and improvements in quality of life

2. Outcome Measures and Relevance

- **EMDMA-001 Trial (Emyria):** Emyria's trial aims to measure outcomes that are clinically relevant to everyday mental health care. The real-world data collected in these trials are designed to capture a broader range of patient experiences, integrating practical variables like healthcare accessibility, patient engagement, and long-term efficacy in a routine clinical setting. These results help Emyria in its mission to **optimize treatment protocols continuously**, improving therapies and providing data that inform **evidence-based IP** creation.
- **MAPS Trial (Lykos):** The MAPS trials have demonstrated significant efficacy in reducing PTSD symptoms after MDMA therapy. In a study of over 100 participants, about **67% of individuals no longer met PTSD criteria after three sessions**, a notable achievement for a treatment-resistant condition. These trials are typically conducted in specialized clinics, with high standards for patient selection and therapeutic consistency. However, the controlled nature of these trials may not capture the diversity of patient needs and treatment responses seen in general clinical practice, limiting their real-world applicability in certain contexts.

3. Clinical Relevance and Real-World Applicability

- **EMDMA-001 Trial (Emyria):** Emyria's approach stands out because it reflects **real-world conditions** rather than the controlled experimental setups commonly used in early-phase trials. This makes its data more applicable to typical clinical settings where patient circumstances, treatment adherence, and healthcare system factors play a significant role in the success of therapy. By focusing on these practical elements, Emyria ensures its findings are more applicable to the diverse patient populations that may benefit from psychedelic-assisted therapies
- **MAPS Trial (Lykos):** While the MAPS trials are groundbreaking, the results may be less directly translatable to everyday clinical settings due to their highly controlled conditions. **The focus on rigorously measuring PTSD symptoms under ideal conditions** does not necessarily reflect the challenges clinicians face in the broader healthcare system, where patients might have co-occurring disorders, varying treatment adherence, or less ideal therapeutic environments

4. Regulatory and Funding Considerations

- **EMDMA-001 Trial:** Emyria's trial is positioned within the **Australian Authorised Prescriber framework**, which enables the company to work directly with patients while receiving regulatory approval to offer MDMA-assisted therapy. In addition to this, Emyria is working with **private health insurers** to establish funding pathways, which could make this therapy more accessible and affordable to a larger patient population, thereby increasing its scalability. Moreover, the continuous refinement of treatment protocols is not only beneficial for patient outcomes but also allows Emyria to **expand its intellectual property** portfolio, further supporting its long-term business model

- **MAPS Trial (Lykos):** MAPS has gained FDA's **Breakthrough Therapy** designation for MDMA-assisted therapy, which accelerates the approval process. However, the regulatory path for MAPS is heavily focused on the U.S. market, and much of the trial data is used to demonstrate safety and efficacy in anticipation of widespread legal approval. Funding for these trials is largely derived from **philanthropy, grants, and private investors**, and the application process is more concentrated in clinical research than in patient accessibility

5. Intellectual Property and Long-term Strategy

- **EMDMA-001 Trial:** By integrating real-world data collection into its trial design, Emyria creates a continuous feedback loop that can inform not only its clinical strategies but also its **IP development**. This data-centric approach helps the company build proprietary treatment models that could be expanded globally, especially as the healthcare system continues to adapt to the inclusion of psychedelics in mainstream therapy. This positions Emyria as a unique player in the market, not just in research but in creating scalable, **evidence-backed treatment solutions**
- **MAPS Trial (Lykos):** While MAPS is pioneering the use of MDMA in PTSD treatment, its focus remains on clinical efficacy and regulatory approval. The intellectual property created in this process is primarily around the therapeutic use of MDMA in specific settings (e.g., PTSD treatment), but MAPS' broader focus on research and public advocacy (through the non-profit arm) limits its immediate commercial advantages compared to Emyria's more commercial approach

*While both Emyria and MAPS have made significant strides in the realm of psychedelic-assisted therapies, Emyria's **real-world approach** provides more immediate clinical relevance for a diverse patient population. The ability to continuously refine treatments based on real-world data gives Emyria an edge in both patient outcomes and long-term **intellectual property development**. Presenting Emyria's data in this context not only highlights its clinical value but underscores how it is better positioned to deliver scalable, adaptable therapies compared to MAPS' more controlled research trials.*

*By emphasizing Emyria's real-world trial data, you can present a compelling case that it not only mirrors the results of MAPS but offers **greater practical applicability**, making it a more attractive option for widespread, future use in mental health care.*

Conclusion: Investment Opportunity in Emyria (ASX:EMD)

Emyria Limited is at the forefront of addressing **critical mental health challenges**, leveraging **innovative therapies** like **MDMA-inspired medicines** and **CBD-based solutions**. The company's focus on **unmet mental health needs**, coupled with **strategic partnerships** and groundbreaking research, positions it as a significant player in the **evolving mental health and PTSD treatment market**.

1. Strong Demand for Psychedelic Therapies

The potential for growth in the **global PTSD market**, projected to reach **USD 19.4 billion by 2032**. The growing recognition of the mental health crisis, especially among high-risk groups like first responders and veterans, presents a compelling demand for alternative therapies like MDMA-assisted therapy. With treatment-resistant PTSD on the rise, Emyria's focus on this niche market positions the company to meet a critical need. As more people seek effective treatments, the market for psychedelic-assisted therapies is expected to expand significantly, particularly in regions with progressive drug policies.

2. Regulatory and Policy Shifts

The regulatory environment is evolving in favor of psychedelic therapies, particularly in the U.S., Canada, and Australia. With high-profile figures like Robert F. Kennedy Jr. and Martin Makary advocating for psychedelic reforms, there's an increasing likelihood of FDA approval for MDMA and psilocybin as treatments for mental health disorders. Kennedy's stance on reforming the FDA's approach and Makary's commitment to data-driven approvals align with broader political and regulatory shifts that could pave the way for rapid adoption of these therapies. The FDA's growing openness to exploring alternative treatments and its recent approval of cannabis studies signal that MDMA therapy could soon receive more favorable consideration.

3. Emyria's Strategic Positioning

Emyria's recent trials targeting first responders and its partnership with the University of Western Australia (UWA) strengthen its position as a leader in psychedelic therapy research. The exclusive licensing agreement with UWA to commercialize serotonin-releasing agents for mental health conditions adds diversification to its pipeline, enhancing future growth prospects. The company's ability to attract funding, as demonstrated by its trading halt for capital raising, indicates that it is preparing to scale its operations and expand its research base.

4. FDA Approval and Market Expansion

While the FDA has yet to approve MDMA for PTSD, recent political developments, including the appointment of reform-minded leaders like Robert F. Kennedy Jr. and Martin Makary, increase the likelihood of approval in the near future. Emyria is well-positioned to benefit from these changes, with its trials and strategic partnerships offering a solid foundation for navigating regulatory approval. As the policy landscape continues to shift toward acceptance of psychedelic therapies, Emyria's products are likely to see greater market acceptance, further driving demand for its therapies.

Final Thoughts

With the convergence of increasing demand, supportive policy changes, and a strong clinical pipeline, Emyria presents a promising investment opportunity. The potential for FDA approval, coupled with the company's strategic partnerships and commitment to advancing mental health treatments, positions it as a leader in the rapidly growing psychedelic therapy market. Investors should consider the long-term growth prospects driven by these regulatory and market developments, which could significantly enhance Emyria's market position in the coming years.

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Three white darts are positioned vertically, with their tips pointing towards the center of a target. The target consists of several concentric white circles on a light-colored surface. The background is a soft, light gray gradient.

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