



A clinical stage biotech informed by patient experience. Tackling unmet needs in neuroscience and mental health.

# Emyria secures \$2M in firm bids from new and existing sophisticated investors; Announces ~\$3.1M non-renounceable entitlement offer

# HIGHLIGHTS

Firm bids received from new and existing sophisticated and professional investors for a placement of \$2m (before costs) at \$0.075 each together with 1 free attaching unquoted option for every 2 shares applied for ("Placement")

\$0.5m cornerstone participation in the Placement by long-time supporter of the Company, Sixty Two Capital ("Lead Manager")

Emyria will also undertake a non-renounceable pro rata entitlement offer on a 1 share for 7.5 shares held basis to raise approximately an additional \$3.1 million ("Entitlement Offer")

Funds from the Placement and Entitlement Offer will be used to fast-track Emyria's mental healthcare programs, including MDMA-assisted therapy for PTSD, novel drug development, and payer engagement, while also supporting potential revenue growth and data collection

**Emyria Limited (ASX: EMD)** ("Emyria", or the "Company") is pleased to announce that it has successfully secured firm commitments from new and sophisticated investors to raise \$2 million (before costs) through an oversubscribed Placement. In conjunction with the Placement, Emyria will initiate a non-renounceable pro rata entitlement offer to raise approximately \$3.1 million (before costs) at the same terms.

#### **Details of the Placement:**

The Placement comprises the issue of approximately 26,666,667 fully paid ordinary shares at \$0.075 each ("Placement Shares") representing a 6.25% discount to the last traded price as at 30 August 2023. In addition, the Placement includes 1 free attaching unquoted option for every 2 shares applied for and issued under the Placement ("Placement Options"). The Placement Options will be exercisable at \$0.12 each and expire 3 years from the date of issue.

The Placement Shares will be issued pursuant to the Company's placement capacity under ASX Listing Rules 7.1 and 7.1A. The issue of the Placement Options are subject to the prior receipt of shareholder approval, which is planned to be sought at a general meeting expected to be held in October 2023 ("General Meeting").

Sixty Two Capital Pty Ltd acted as Lead Manager to the Placement. As partial consideration for the services provided by the Lead Manager, the Company has agreed to issue up to 6,000,000 unquoted options to the Lead Manager (or its nominees) each exercisable at \$0.12 each and expiring 3 years from the date of issue. The issue of the options to the Lead Manager is subject to the prior receipt of shareholder approval, planned to be sought at the General Meeting.

The Lead Manager will also contribute \$500,000 in the Placement. The issue of Placement securities to the Lead Manager (or its nominees) is subject to the prior receipt of shareholder approval, which is planned to be sought at the General Meeting.



#### **Details of the Entitlement Offer:**

Eligible shareholders will be given the opportunity to subscribe for new shares in the Company on the basis of 1 new share for every 7.5 existing shares held on the Record Date (defined below). Eligible shareholders will also receive 1 free attaching unquoted option for every 2 new shares applied for and issued under the Entitlement Offer. The options will be exercisable at \$0.12 each and expire 3 years from the date of issue.

Lead Manager has a first right of refusal to place any shortfall from the Entitlement Offer.

Further information will be sent to eligible shareholders in a prospectus expected to be announced on 6 September 2023 and made available to eligible shareholders on 18 September 2023 ("Entitlement Offer Prospectus").

The Entitlement Offer Prospectus and accompanying personalised entitlement and acceptance forms will contain instructions on how to apply to participate in the Entitlement Offer. Eligible shareholders are encouraged to carefully read the Entitlement Offer Prospectus for further details relating to the Entitlement Offer.

#### Indicative Timetable:

Event	Date (2023
Trading halt lifted Announcement of Entitlement Offer and results of Placement Appendix 3B for Placement and Entitlement Offer	4 Septembe
Lodgement of Entitlement Offer Prospectus with ASIC	5 Septembe
Announcement of Entitlement Offer Prospectus and investor presentation on ASX	6 Septembe
Entitlement Offer "Ex" date Expected date for quotation of new shares issued under the Placement	12 Septembe
Record Date to identify security holders entitled to participate in the Entitlement Offer	13 Septembe
Entitlement Offer Prospectus and personalised entitlement and acceptance forms made available to persons entitled and announcement that this has occurred Entitlement Offer opening date	18 Septembe
Entitlement Offer closes at 5:00pm (AWST)	28 Septembe
Announcement of the results of the Entitlement Offer Appendix 2A and 3G for Entitlement Offer	5 Octobe

The Company advises that StocksDigital ("SD") has been engaged to provide investor relations support to Emyria, and will be issued 5m shares and 2.5m options as payment for A\$375,000 worth of services to be provided to the Company across a 30 month initial engagement period (shares to be issued at a deemed issue price of A\$0.075 per share). Shares issued to SD will be under the Company's Listing Rule 7.1 placement capacity, with the issue of the options being subject to the receipt of prior shareholder approval. All Shares issued to SD will be subject to voluntary hold conditions in accordance with SD's trading policy.<sup>7</sup> The engagement of SD is otherwise on customary terms.



#### **Use of Funds:**

The capital secured from the Placement and the Entitlement Offer will support Emyria's strategic objectives in mental healthcare, particularly in new drug development and in addressing the needs of the estimated 400,000 Australians impacted by severe PTSD. <sup>1</sup> Our near-term focus is on leveraging our multidisciplinary team and fit-for-purpose facilities to deliver MDMA-assisted therapy, a modality currently showing promise in Phase 3 clinical trials for PTSD. <sup>2</sup> Emyria's unique approach delivers direct patient benefits while also generating revenues and robust real-world data that help advances the Company's future initiatives in mental healthcare innovation via proprietary drug development and innovative care delivery.

### Launch MDMA-assisted Therapy:

Funds will support patient participation in Emyria's ethics-approved MDMA-assisted therapy trial (EMDMA-001) as well as Emyria's Authorised Prescriber ("AP") led care programs. The Company has already submitted AP applications for its leading psychiatrists and is awaiting the arrival of drug supply from Canada to commence treatment having already obtained all necessary import permits. <sup>3</sup>

#### **Engage Payers:**

A dedicated part of the funding will strategise engagement with healthcare payers. The aim is to help demonstrate the cost effectiveness of Emyria's care models to enhance patient affordability.

#### Scale Clinical Offerings & Revenues:

Funds raised will support the optimisation of both ketamine-assisted <sup>4</sup> and psilocybin-assisted therapy models and their roll-out across existing sites and new clinical partners, thereby contributing to potential new revenue streams and the collection of robust data for these emerging treatment approaches.

#### **Advance Novel MDMA Analogues:**

The investment will advance Emyria's novel MDMA analogue program, particularly in two leading series. The first addresses L-DOPA induced dyskinesia ("LID") in Parkinson's disease ("PD") patients. PD is the fastest-growing neurodegenerative disorder globally. L-DOPA is a dopamine replacement and first-line treatment for PD but can cause a movement disorder (dyskinesia) in approximately 80% of PD patients. 30% of PD patients develop LID within just three years of L-DOPA initiation.<sup>5</sup> The market need for a treatment for LID is significant. The second novel MDMA analogue series aims to produce faster-acting MDMA for PTSD treatment. Alongside, Emyria is working to secure robust "new chemical entity" patents and strategic partnerships.

#### **Advance Ultra-Pure Cannabinoid Dose Forms:**

The funds will further the clinical trials and registration of our Ultra-Pure cannabinoid products EMD-RX5, EMD-RX7, and EMD-RX9. For EMD-RX5, which is in Phase 3 trials for anxiety and stress, a portion will be allocated for manufacturing improvements (see page 4). A term sheet with Aspen Pharmacare Australia for commercialisation remains active. For EMD-RX7 and EMD-RX9, preclinical evaluations continue in association with the U.S. National Institutes of Health ("NIH"). <sup>6</sup>



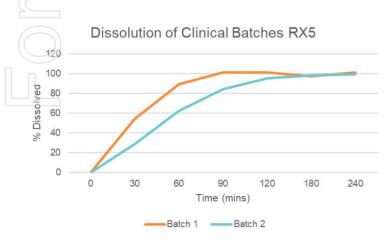
## **EMD-RX5 Trial Update:**

As mentioned in the Company's June 2023 Quarterly Report \*, progress for our Phase 3 EMD-RX5 has slowed while the Company navigates delays of EMD-RX5 with our Contract Drug Manufacturing Organisation ("CDMO").

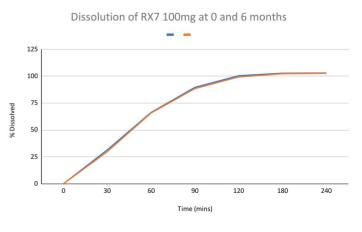
During routine quality assessments a difference in dissolution rates between two batches of the product was identified. For clarity, "dissolution rates" refer to how quickly a substance dissolves in a simulated solvent. For all products seeking registration, consistency in the dissolution rates is expected between batches of the same product as well as over time. In this case, Batch 1, used for the first half of the trial, and the newly introduced Batch 2 showed a discrepancy in their dissolution rates (see Fig 1). It's important to note that both Batches still met all stringent guidelines for safety and CBD purity and that there are no safety concerns; the issue is solely with the dissolution rates.

Having used all of Batch 1 in the trial, the Company has paused recruitment to investigate the matter with Batch 2 further, in line with the rigorous standards set by the Therapeutic Goods Administration ("TGA"). Our preliminary investigations indicate that the issue is likely a manufacturing variation affecting one of the excipients (inactive substances used as carriers for the active ingredients). The Company has ruled out other potential causes (for example chemical changes or the outer capsules). A new manufacturing method is being developed, using an updated manufacturing process and a new batch will be produced and monitored for stability. An update on this program is expected towards end of H2, 2023. In the meantime, Emyria's Contract Research Organisation ("CRO") is conducting a full quality review of all study data gathered to date (~50% recruitment), to ensure readiness for analysis when appropriate.

Emyria's portfolio also includes two other Ultra-Pure CBD capsules, RX7 and RX9. These products remain unaffected by stability or dissolution issues. RX7 has shown remarkable stability and bioavailability (the rate at which a drug is absorbed into the bloodstream), outperforming other registered CBD products in preclinical assessment. RX9 is also progressing well, with method development underway. Both candidates hold promise as high potency, highly bioavailable, solid oral dose forms of Ultra-Pure CBD nearing readiness for Phase 1 clinical trials.



<u>Figure 1:</u> Difference in dissolution rates between Batch 1 and Batch 2 of EMD-RX5 at 6 months



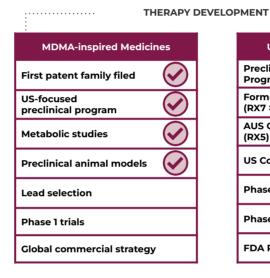
<u>Figure 2:</u> No difference in dissolution rates between a single batch of EMD-RX7 showing tight consistency over time



**Dr. Michael Winlo, CEO of Emyria**, commented: "We're thrilled by the strong support for our recent Placement, particularly from our long-term investors. We're equally excited to extend the same investment terms to our shareholders through an Entitlement Offer. This capital will advance our mental healthcare programs, especially our efforts to combat severe PTSD, and accelerate our drug development initiatives. Emyria's unique approach serves patients grappling with complex mental health issues while generating revenues and real-world data to lay a solid foundation for our future growth and innovation.""

#### **RECENT TRACTION & UPCOMING MILESTONES**

# Advanced mental health care Acquisition of leading psychological trauma service Commencement of MDMA-assisted therapy Expand treatment offerings Authorised Prescriber approvals Expansion of clinical footprint Engagement with payers Leverage data platform





#### **References:**

- 1. https://www.aihw.gov.au/reports/mental-health-services/stress-and-trauma
- 2. Mitchell, J.M., Bogenschutz, M., Lilienstein, A. et al. MDMA-assisted therapy for severe PTSD: a randomized, double-blind, placebo-controlled phase 3 study. Nat Med 27, 1025–1033 (2021)
- 3. See ASX release 08 June 2023
- 4. See ASX release 08 August 2023
- 5. See ASX release 04 April 2023
- 6. See ASX release 28 November 2022
- 7. https://nextinvestors.com/disclosure-policy/

This release has been approved by the Board of Emyria.

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#### FOR FURTHER INFORMATION

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# ABOUT EMYRIA | emyria.com

generates

informs

- **Emyria Limited** is a clinical services and drug development company with a focus on revolutionising patient outcomes in neuroscience and mental health via:
  - Clinical Service Delivery: With Emerald Clinics, and the recent acquisition of the Pax Centre, a leading psychological trauma center, Emyria delivers evidence-based and emerging therapies for mental health and other unmet needs.
  - Proprietary Real-World Data (RWD): Through its advanced data platform powered by Palantir, Emyria collects robust and ethically-sourced Real-World Data to improve its care models and support its distinct therapy and drug development initiatives.
  - **Drug Discovery & Development:** Guided by its RWD, Emyria is developing several proprietary Ultra-Pure cannabinoid dose forms and advancing them towards registration. In parallel, we are establishing one of the world's largest libraries of MDMA-like compounds in partnership with the University of Western Australia.



**Investorhub.emyria.com** Interact with Emyria's announcements and updates by asking questions and comments, which our team can respond to where possible.



# ABOUT The Pax Centre | paxcentre.com.au



The Pax Centre specialises in treating individuals grappling with the psychological impacts of traumatic experiences. Our treatment approach is highly personalised, addressing a wide range of mental health issues, from PTSD and depression to anxiety disorders and substance abuse, often stemming from various life traumas.

Complex trauma, characterised by repeated, relational traumatic events often occurring during developmental stages, requires specialised attention due to its pervasive and lasting impact. In these cases, The Pax Centre prioritises early diagnosis and evidence-based treatments.

We also focus on proactive strategies for health expansion and personal growth, empowering our clients with skills and tools to improve wellbeing and performance. At the Pax Centre, we believe in transforming lives through focused, evidence-based mental health care

# ABOUT Emerald Clinics | emeraldclinics.com.au



Emerald Clinics is an Australian-based, patient-centric clinical service specialising in providing treatments for patients with complex and chronic conditions, where traditional therapies might not have yielded satisfactory results.

Leveraging our deep expertise with unregistered medicines, such as cannabinoids, we strive to pioneer and personalise care for our patients. Our robust, ethically-sourced data collection methods underpin our commitment to improving patient outcomes and advancing healthcare innovation.

**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.