

Emyria expands psychiatry advisory to advance psychedelic-assisted therapies and novel MDMA-analogue development

Highlights:

- Consultant general and pain Psychiatrist, Dr. Jeremy Tannenbaum has been appointed to Emyria's clinical advisory to support Emyria's psychedelic-assisted therapy programs

- Dr. Tannenbaum's interests cover the emerging use of psychedelic-assisted psychotherapy and other potential uses of psychedelics as well as the holistic treatment of complex pain conditions

- Dr. Tannenbaum completed a clinical observership with leading psychedelic-assisted therapy pioneers, Professor David Nutt (Imperial College, UK) and Dr Robin Carhart-Harris in the early stages of their research into the therapeutic role of psilocybin

- The global mental health market is estimated at US\$100Billion per year, with psychedelic treatments like MDMA-assisted therapy estimated to reach US\$10B in annual sales once clinical safety, efficacy and cost-effectiveness has been demonstrated [1]

- Emyria's goal is to develop a leading, scalable, evidence-based model for MDMA-assisted psychotherapy delivery

- A TGA-commissioned independent report into the risks and health benefits of MDMA and psilocybin, led by a team of international experts, is due for release on September 30th, 2021 [2]

Emyria Limited (ASX: EMD) (Emyria or the Company), a data-backed drug development and care delivery company, is pleased to announce the appointment of Consultant Psychiatrist - Dr. Jeremy Tannenbaum - to Emyria's clinical advisory to help advance Emyria's psychedelic-assisted research and related drug development programs.

Dr. Tannenbaum's interests and training covers the interface between psychiatry and pain medicine as well as the emerging use of psychedelic-assisted psychotherapy and other potential uses of psychedelics.

At the completion of further training, Dr. Tannenbaum will be one of only a small number of specialist medical practitioners in Australia to hold dual qualifications in both Psychiatry and Pain Medicine.

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For Emyria, Dr. Tannenbaum will advise on:

- **EMDMA-001**, Emyria's MDMA-assisted psychotherapy trial for Post-Traumatic Stress Disorder (PTSD)
(See ASX announcement 29 Jun 2021)
- Emyria's **MDMA-analogue** drug discovery and screening pipeline
(See ASX announcement 05 Aug 2021)
- Emyria's research and development of novel approaches for people with complex pain conditions including cannabinoids
(See ASX announcement 07 Jun 2021)

Dr. Tannenbaum's relevant clinical and research experience:

- Fellowship in Psychiatry and in the final stages of completing his dual Fellowship qualification as a Specialist Pain Medicine Physician
- Clinical observership with **Professor David Nutt** and **Dr Robin Carhart-Harris** at Imperial College studying the early stages of their clinical research into use of psychedelics to treat psychiatric disorders
- Specialist in the holistic assessment and management of psychiatric disorders and persistent pain conditions.



Special interests in:

- The emerging therapeutic role of psychedelic assisted psychotherapy for difficult to treat mental illness
- Exploring the potential for psychedelics in other medical conditions
- Stellate ganglion blocks for PTSD
- Repetitive Transcranial Magnetic Stimulation (rTMS) for difficult to treat conditions including depression, PTSD, pain and other indications
- Ketamine infusion therapies for pain and mental health conditions
- Completed a survey of doctors' views and attitudes regarding medicinal cannabis in Western Australia, 2019
- Conducted a pooled analysis investigating the link between cardiovascular and serotonergic function in anxiety disorders
- Current participant Certificate in Psychedelic-Assisted Therapies (CPAT)

Emyria's Managing Director, Dr. Michael Winlo, said: "We're delighted to welcome Dr. Jeremy Tannenbaum to our world-class clinical advisory."

Dr. Tannenbaum has a unique combination of specialist training and research experience covering psychiatry, pain medicine and the use of psychedelic-assisted therapy to address major mental health concerns.

We believe Dr. Tannenbaum's unique and diverse training in psychiatry and pain medicine can greatly advance Emyria's MDMA-assisted psychotherapy trials for Post-Traumatic Stress Disorder, our MDMA-analogue discovery and screening program, and also support Emyria to evaluate the use of cannabinoid and other novel therapeutic approaches to address the biopsychosocial aspects of complex pain management."

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Dr. Jeremy Tannenbaum, said *“Psychedelic-assisted therapy is showing great promise in treating complex and difficult-to-treat mental health conditions. In order to reach the patients most in need, further research and clinical evidence is required. I’m pleased to support Emyria’s unique model of care delivery, evidence generation and treatment development, which is well-placed to evaluate how best to deliver these treatments consistently and safely.”*

Psychedelic-assisted therapy offers potential for a range of difficult-to-treat mental health difficulties

There is a strong and emerging body of international evidence that shows that substances such as ketamine, psilocybin, and 3,4-methylenedioxymethamphetamine (MDMA), when used in a controlled environment and supported by psychotherapy, offer a promising new approach to treating major mental illnesses that are resistant to first-line treatments. [3]

The Multidisciplinary Association for Psychedelic Studies (MAPS) recently announced results of a Phase 3 trial of MDMA-assisted therapy for PTSD and reported a significant reduction in PTSD symptoms compared to those who received placebo with therapy ($p < 0.0001$). 67% of the group who received MDMA, compared to 32% of the group who received placebo, no longer qualified for a PTSD diagnosis after three treatment sessions. [4]

MDMA-assisted therapy for PTSD has been granted ‘Breakthrough Therapy’ status for treatment of post-traumatic stress disorder (PTSD) by the US Food and Drug Administration (FDA). [5]

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TGA’s position on psychedelics

Australia’s Therapeutic Goods Administration (TGA) is currently considering rescheduling MDMA and psilocybin. If successful, rescheduling would move these medicines from Schedule 9 to Schedule 8 (which deals with Controlled Medicines), the same category as THC-containing cannabinoid medicines.

The TGA’s Scheduling Delegate (decision maker) has deferred the final decision on applications to down-schedule MDMA and psilocybin from schedule 9 (prohibited drug) to schedule 8 (controlled drug) pending a review into the therapeutic value, risks and benefits to public health outcomes for these substances. An Independent Expert Panel has been established to undertake this review. The Panel’s Report will be published on the TGA website on 30 September 2021 ahead of consideration by the Advisory Committee on Medicines Scheduling [2].

This announcement has been approved and authorised for release by the Managing Director of Emyria Limited.

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For further information:

Dr. Michael Winlo
Managing Director
1300 436 363
mwinlo@emyria.com

Lexi O'Halloran
Media/Investor Relations
+ 61 (0) 404 577 076
lexi@janemorganmanagement.com.au

Andrew Williams
Media Relations
+61 (0) 412 614 125
andreww@profilemedia.com.au

References

[1]

<https://www.forbes.com/sites/willyakowicz/2021/06/23/the-future-of-psychedelic-medicine-might-skip-the-trip-rick-doblin-bryan-roth-mindmed-darpa-maps/?sh=60546133244f>

[2] <https://www.tga.gov.au/independent-expert-panel-mdma-and-psilocybin>

[3] <https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/15-million-for-development-of-innovative-therapies-for-mental-illness>

[4] <https://maps.org/news/media/9122-maps-phase-3-trial-of-mdma-assisted-therapy-for-ptsd-achieves-successful-results-for-patients-with-severe-chronic-ptsd>

[5]

<https://maps.org/news/media/6786-press-release-fda-grants-breakthrough-therapy-designation-for-mdma-assisted-psychotherapy-for-ptsd,-agrees-on-special-protocol-assessment-for-phase-3-trials>

About Emyria (www.emyria.com)

Emyria Limited is a clinical drug development and care delivery company.

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Treatments target large unmet needs and are focused on obtaining approval ("registration") with major global regulators. Emyria's treatment development programs are informed by insights generated from extensive analysis of **Emyria Data** - deep, ethically-sourced clinical evidence that is gathered with patients across Emyria's independent clinical services (**Emerald Clinics** - www.emeraldclinics.com.au)

Emyria Data provides deep treatment insights and is therefore a source of unique IP, strategically designed drug development and personalised care programs.

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.