ASX Announcement

20 Dec 2021

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Emyria to expand Real World Data assets for MDMA-assisted therapy trials by incorporating wearables monitoring

Highlights:

- Emyria has signed a letter of intent (LOI) with Cydelic - a private company based in Seattle developing tools and technologies that help track the wellbeing of patients before, during and after psychedelic-assisted therapy
- Emyria plans to work with Cydelic across all of its psychedelic-assisted therapy programs to capture unique biometric data that can assist with real-time patient safety and dose response analysis and registration of psychedelic-assisted therapy
- Emyria's phase 2b MDMA-assisted therapy trial for severe Post Traumatic Stress Disorder (PTSD), **EMDMA-001**, developed with registered charity Mind Medicine Australia (MMA), *[See ASX announcement 05 May 2021]* will be the first program to incorporate Cydelic technology and is expected to be one of the first programs in the world to incorporate remote patient monitoring within MDMA-assisted therapy
- EMDMA-001's leading psychotherapist is MMA's clinical lead Nigel Denning who has completed therapist training with the Multidisciplinary Association for Psychedelic Studies (MAPS) this week and is a co-lead of MMA's Certificate of Psychedelic Assisted Therapy (CPAT)
- The recent TGA decision not to reschedule MDMA from Schedule 9 to 8 at this time places greater importance on clinical trials and Real-World Data to develop evidence-based practices for these treatments to improve patient access
- Emyria is committed to advancing its proprietary MDMA-analogue program to deliver new registered treatments for a range of psychiatric and neurological indications

Emyria Limited (ASX: EMD) (Emyria or the Company), a data-backed drug development and care delivery company, is pleased to announce it has entered into a letter of intent with innovative biometric software and hardware company, Cydelic, based in Seattle, USA.[1]

Cydelic is developing a biometric monitoring platform to assist patients and their therapists before, during and after psychedelic-assisted therapy.

The TGA's recent decision not to reschedule MDMA and psilocybin from Schedule 9 to Schedule 8 at this time, highlighted the importance of replicating recent statistically significant clinical trial results [2] in *"real-world settings"* [3]. The TGA also emphasised that *"translation from a clinical trial setting to the community will depend on adequate expertise, procedures and ethical standards."*

Cydelic's remote monitoring technology will be incorporated into Emyria's Real-World Data platform, powered by Palantir Foundry [4] to help track multiple physiological parameters before, during and after an MDMA-assisted therapy trial for PTSD (EMDMA-001) developed with MMA. Robust physiological measurements may assist in patient selection, safety monitoring during treatment, dose-response analysis as well as tracking long-term safety and durable changes to quality of life.

A validated system for tracking patient physiology alongside psychotherapy could help therapists monitor patient safety while also supporting the standardisation, scalability, registration and reimbursement of psychedelic-assisted therapies.

Physiological measures that Emyria plans to track using the Cydelic platform include:

- **EEG ("brainwaves")** - There are many EEG biomarkers associated with PTSD. The most common and prominent biomarker is alpha band-related parietal asymmetry (ABPA) which is an alpha power imbalance between the left and right hemispheres within the parietal lobe.
- **Heart rate (HR) and heart rate variability (HRV)** - these measures can change in acute emotional or physiological distress.
- **Activity and sleep** - may be helpful in understanding changes in sleep routines by comparing patterns before and after treatment
- **Electrothermal activity and skin temperature** - which may help measure depth of emotional response

Emyria's Managing Director, Dr. Michael Winlo said: *"Psychedelic-assisted therapy is showing tremendous promise for patients suffering the most debilitating mental health challenges.*

The recent decision by the TGA not to reschedule MDMA and psilocybin at this time highlights the important role companies like Emyria, and our innovative partners, will play to further develop these treatments through clinical studies and careful data collection. This will benefit from Real-World Data from wearable technologies and novel treatment development. Emyria is involved in all of these areas.

We are now delighted to be working with Cydelic to add cutting-edge remote monitoring to our psychedelic-assisted therapy programs and clinical trials.

Once a contract is finalised, Emyria will utilise a suite of remote patient monitoring wearables to closely track the safety and well-being of patients before, during and after participation in psychedelic-assisted therapy clinical trials, starting with the MDMA-assisted therapy trial for PTSD which has been developed in partnership with Mind Medicine Australia.

By paying close attention to a patient's physiology with remote monitoring we can build a unique Real-World Data asset that can help clinicians optimise the patient experience and improve clinical outcomes. It is hoped this unique data can also help with the registration and reimbursement of these treatments.

I look forward to updating the market with further progress and results as we advance our development milestones in the coming months."

An early goal of the partnership is to develop a deeper understanding of how to implement wearables into psychedelic-assisted therapy in order to build unique and robust real-world data that can assist with safety and efficacy research.

The partnership will provide Emyria with unique wearable and biometric data during planned trials. This data, when combined with clinical outcomes measurements, will be owned by Emyria and are expected to extend the depth and utility of Emyria's Real World Data (RWD). Emyria's RWD helps generate safety and efficacy evidence for novel treatments and assists Emyria pursue registration of the most promising new treatments with global regulators - a major commercial objective for Emyria. Emyria will control and own all clinical and device data, and Cydelic will receive anonymised, non-clinical, device data for technical support only.

The non-binding letter of intent with Cydelic is to develop a formal contract within the next 30 days to cover the provision and configuration of remote monitoring devices ("wearables") and proprietary software integrating data received from these devices. Specifically, Cydelic will help select the most suitable monitoring devices for each use case and provide the necessary technical support to ensure that all data can flow securely, and in real-time, into Emyria's Real World Data platform where it can be integrated with additional clinical data.

Each party will bear its own costs for the development of the contract which will be prepared over the next 30 days. If no agreement is reached within that time, the LOI will lapse. Payments to Cydelic for these services will be determined on a trial-by-trial and program-by-program basis depending on the monitoring and technical requirements of each trial or program. Pricing for these services will be determined during negotiations of the formal agreement.

The first engagement is expected to cover Cydelic's assistance with Emyria's EMDMA-001 trial protocol, currently under review by MAPS. EMDMA-001 is expected to commence towards the end of Q1, 2022 subject to receipt of ethics approval and a contract from MAPS. Thereafter, services may be provided for future trials and programs at Emyria's discretion.

Emyria has deep expertise in Real World Data having built one of the world's largest RWD assets for pharmaceutical grade cannabinoid therapy from over 5,000 patients.

Emyria has also successfully developed and registered a TGA-approved, Class II medical device - Openly - which can track a variety of cardiovascular biomarkers using a patient's smartphone. (*See ASX announcement 12 May 2021*)

This announcement has been approved for release by the Board of Emyria Limited.

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For more information on EMDMA-001 and **Emyria's remote monitoring innovations** and **progress in psychedelic-assisted therapy development**, please see:

- First partnership with Mind Medicine Australia (MMA) (19 Nov 2020)
- Emyria adds PTSD-expert psychiatrist to advisory (01 Feb 2021)
- Emyria wins major remote monitoring grant (05 Feb 2021)
- Emyria and MMA announce MDMA-assisted therapy trial for PTSD (05 May 2021)
- Emyria obtains TGA registration for remote monitoring app Openly (12 May 2021)
- Emyria appoints Principal Investigator for EMDMA-001 (29 Jun 2021)
- Emyria to develop novel MDMA analogues with UWA (05 Aug 2021)
- Emyria appoints neuropharmacologist for MDMA program (20 Aug 2021)
- Emyria appoints consultant psychiatrist to advisory (16 Sep 2021)
- Emyria announces positive MDMA-analogue screening results (15 Dec 2021)

References:

[1] https://cydelic.tech
[2] https://maps.org/mdma/ptsd/
[3]https://www.tga.gov.au/scheduling-decision-final/notice-final-decisions-amend-or-not-amend-current-poisons-standard-relation-psilocybin-and-mdma
[4] see ASX announcement 07 October 2021

About Emyria (www.emyria.com)

Emyria Limited is a data-backed clinical drug development and care delivery company focused on accelerating treatment development and improving patient care.

Emyria's Treatments target unmet needs and are focused on obtaining approval from major global regulators. Emyria's drug 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.

About Cydelic (www.cydelic.tech)

Cydelic is a Seattle based biomedical device company focused on developing precision wearable devices for psychedelic assisted therapy. The Cydelic platform utilizes a suite of sleek, unobtrusive wearable devices that allows therapists to track subtle changes in patient physiological and emotional states throughout the entire course of therapy.

By gathering multi-modal data across a wide spectrum of biomarkers, the Cydelic platform can assess a patient's response to therapy using a proprietary Emotional Computing Library (ECL) designed specifically to track states of high emotional engagement in response to psychedelic therapy. The Cydelic console also offers secure real-time streaming of patient biodata, allowing multiple therapists to remotely monitor a patient's vital signs from any internet connected device.

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.