ASX Announcement
13 Feb 2023

emyria

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

Emyria secures clinical-grade MDMA supply for Australian patients

HIGHLIGHTS

Emyria has secured sufficient clinical-grade MDMA to support MDMA-assisted therapy for over 70 patients after the TGA rescheduling of MDMA comes into effect after July 1st 2023 [1].

Emyria is establishing a network of research-oriented therapists and psychiatrists and is helping ready their sites and care teams to provide MDMA-assisted therapy - via ethics approved clinical trials and the Authorised Prescriber pathway - to appropriately diagnosed patients from July 1st 2023.

Emyria to explore licencing models for specialist groups to access Emyria's MDMA supply and care model (EMDMA-001).

Emyria Limited (ASX: EMD) (Emyria or the Company), a clinical stage biotech that operates clinical services, has secured a supply of clinical-grade MDMA for an initial cohort of Australian patients through Canadian manufacturer PharmAla, and facilitated by Mind Medicine Australia, when the rescheduling of MDMA comes into effect, July 1st 2023.

The procurement of patient-ready, GMP-grade MDMA is highly challenging due to strict Good Manufacturing Practice standards, US supply quota restrictions [2] and limited global manufacturers. PharmAla is one of the only companies able to export GMP-grade MDMA.

Emyria intends to make the MDMA available to partner psychiatrists with Authorised Prescriber status or under ethics-approved clinical trials, and is actively collaborating with clinical partners to ensure their readiness for MDMA-assisted therapy by supporting clinician training and data monitoring.

Emyria's Managing Director, Dr Michael Winlo said: *"Emyria has expertise delivering treatments to patients with substances listed under Schedule 8 and 9 while generating Real-World Evidence to support care model improvement and novel drug development.*

To support its partners to provide MDMA-assisted therapy from July 1st, Emyria has secured a short-term supply of patient-ready MDMA that can be provided within a comprehensive care model (EMDMA-001) together with appropriately trained and reputable care providers.

Our approach of participating in care delivery also supports our analogue program."

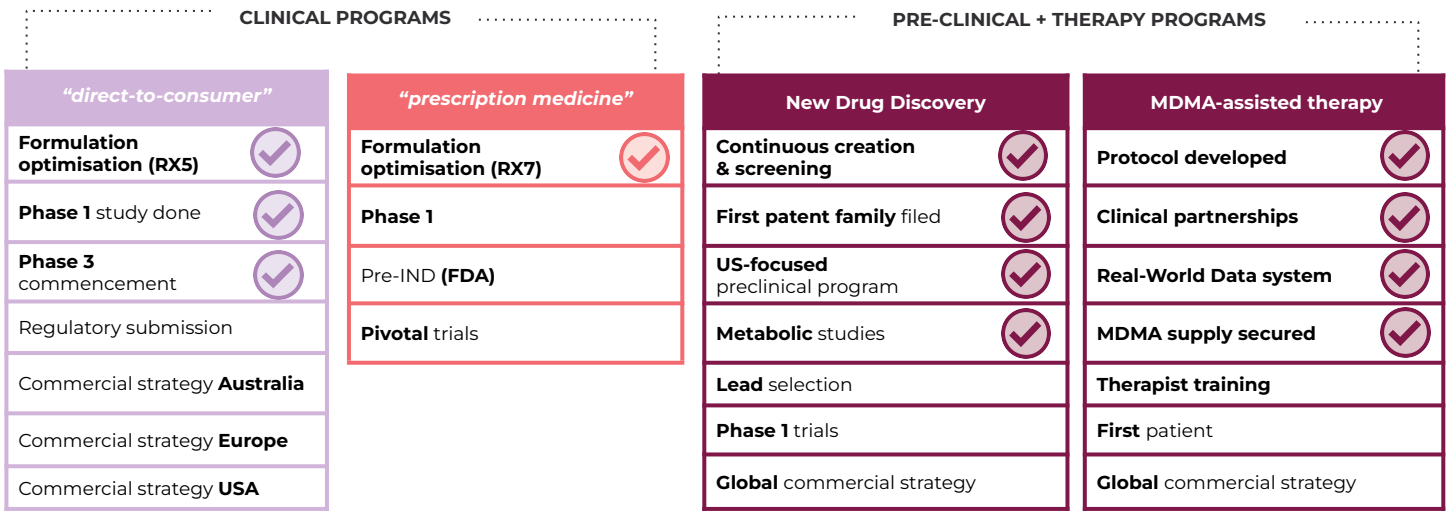
1. https://www.tga.gov.au/sites/default/files/2023-02/notice-of-final-decision-to-amend-or-not-amend-the-current-poisons-standard-june-2022-acms-38-psilocybine-and-mdma.pdf accessed 05 Feb 2023
2. https://www.federalregister.gov/documents/2022/12/02/2022-26351/established-aggregate-production-quotas-for-schedule-i-and-ii-controlled-substances-and-assessment

Australia will be one of the first countries to allow patient access to MDMA-assisted therapy. Securing a reliable, clinical-grade supply of MDMA poses significant challenges due to its highly regulated nature, requiring specialised knowledge, licences, and permissions from regulators and law enforcement. The supply agreement with PharmAla helps ensure Emyria's clinical partners will be ready to support safe and scalable MDMA-assisted therapy while complying with TGA restrictions regarding Authorised Prescriber status.

The recent rescheduling of MDMA by the TGA following applications by Mind Medicine Australia also opens a pathway to registration and reimbursement for Emyria's MDMA-inspired compounds, which are being developed with the University of Western Australia for a range of neuropsychiatric disorders.

Emyria is advancing its drug discovery program in Australia and the United States to identify novel, MDMA-like compounds with therapeutic potential, while collaborating with local clinical partners to improve patient access and ongoing research.

UPCOMING MILESTONES



- This release has been approved by the Board of Emyria. -

FOR FURTHER INFORMATION

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ABOUT EMYRIA | emyria.com

Emyria Limited is a clinical drug development and care delivery company focused on accelerating drug development and improving patient outcomes in neuroscience and mental health via:

- **Drug Development:** Multiple, proprietary, Ultra-Pure cannabinoid dose forms suitable for registration against multiple indications. Emyria's first dose form, EMD-RX5, is in Phase 3 trials.
- **New Drug Discovery:** Inspired by MDMA, Emyria is developing one of the world's largest libraries of MDMA-like compounds with partner, the University of Western Australia.
- **Proprietary Real-World Data (RWD):** Emyria gathers robust and ethically-sourced data with patients cared for at Emyria's own specialist clinical service (Emerald Clinics). Emyria RWD can help support drug development and care model improvement.

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.

About PharmAla Biotech

PharmAla Holdings Inc. (CSE: MDMA) is a biotechnology company focused on the research, development, and manufacturing of MDXX class molecules, including MDMA. PharmAla was founded with a dual focus: alleviating the global backlog of generic, clinical-grade MDMA to enable clinical trials, and to develop novel drugs in the same class. PharmAla is the first publicly-traded company to manufacture clinical-grade MDMA. PharmAla's research and development unit has completed proof-of-concept research into ALA-002, PharmAla's lead drug candidate. PharmAla is a "regulatory first" organization, formed under the principle that true success in the psychedelics industry will only be achieved through excellent relationships with regulators.

About Mind Medicine Australia

Mind Medicine Australia exists to help alleviate the suffering and suicides caused by mental illness in Australia through expanding the treatment options available to medical practitioners and their patients. We are focussed on the availability of safe and effective psychedelic-assisted treatments to treat a range of mental illnesses supported by clinical data. Mind Medicine Australia is a registered charity founded by Tania de Jong AM and Peter Hunt AM. We are supporting clinical research and working towards regulatory-approved and evidence-based psychedelic-assisted therapies. We operate as a peak body that connects medical practitioners, consumers, academia, government, industry, regulatory bodies, philanthropists, investors and other stakeholders.

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.