

ASX Announcement
04 Apr 2023

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

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Emyria and Aspen Australia sign exclusive binding licensing and commercialisation term sheet

HIGHLIGHTS

Aspen Australia to support the registration and commercialisation of EMD-RX5 as an over-the-counter (OTC) treatment in Australia

Aspen Australia is one of Australia's leading pharmaceutical companies, and a subsidiary of Aspen Pharmacare Holdings (JSE:ASP, Market Cap ~$6.7B) a multinational pharmaceutical company

Emyria will receive a royalty of up to 10% based on annual net sales, with aggregate milestone payments of $400,000 for satisfying agreed milestones

EMD-RX5 is currently in Phase 3 clinical trials and is aiming to be the first CBD product registered as an OTC treatment in Australia

EMD-RX5 has a Large Potential Patient Market: Mild anxiety and stress affect up to 15% of the adult population [1], with a higher prevalence in patients with chronic disease, such as chronic pain, which affects around 2.8 million adults in Australia [2]; No OTC treatment currently available for initial target indication; EMD-RX5 has the potential to address a significant unmet need in the OTC market

Emyria Limited (ASX: EMD), (Emyria or the Company) a clinical stage biotech, has entered into a binding Term Sheet (Agreement) with Aspen Pharmacare Australia (**Aspen Australia**) for the licensing and commercialisation of EMD-RX5.

EMD-RX5 is Emyria's first, Ultra-Pure CBD capsule targeting TGA registration as an over-the-counter (OTC) treatment for the symptoms of mild stress and anxiety for patients with a chronic health condition.

EMD-RX5 is currently in Phase 3 clinical trials and aiming to be the first to market. It is a solid capsule form medication, a preferred dosage form for patients and prescribers.

Aspen Australia is a subsidiary of Aspen Holdings (JSE:ASP) - has a comprehensive portfolio of over 140 brands of both Prescription and OTC medicines which cover a wide range of therapeutic categories. Aspen Australia has significant sales and marketing capabilities with a team of ~80 sales and marketing heads to support the successful commercialisation of EMD-RX5. [3]

Aspen Australia will provide funding and resources to support the development and regulatory approvals for EMD-RX5 in Australia. Additionally Aspen Australia will have the exclusive right to market, sell and distribute EMD-RX5 in Australia.

Aspen Australia has full GMP manufacturing capabilities at their site in Dandenong, Victoria and will retain the rights to evaluate the opportunity to manufacture EMD-RX5 locally.

Aspen Australia also retains a first right of refusal to sell and distribute EMD-RX5 for OTC indications in New Zealand. Both Aspen and Emyria will negotiate in good faith to explore OTC market opportunities in other countries in which Aspen operates.

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Aspen Australia is a leading and fully integrated pharmaceutical in with a comprehensive portfolio of products, covering a wide range of therapeutic health categories.



The Aspen Australia range includes over 140 BRANDS and **500 different stock keeping units (SKUs)** spanning branded, prescription & consumer health products

Doctors have consistently ranked Aspen's prescription field force in the top pharmaceutical companies in Australia.



Aspen will leverage their highly experienced prescription and OTC sales teams as well as their fully integrated in-house support functions to assist in the registration of EMD-RX5.



Aspen's CEO, Trevor Ziman said: *"Aspen aims to be leaders in every product category we operate in. We are excited to continue this tradition by partnering with Emyria and supporting the registration and commercialisation of their unique product with large potential in the Australian market. We look forward to a long and successful partnership."*

Emyria's Managing Director, Dr Michael Winlo said: *"Emyria expects to become one of the first companies to register a CBD product for the rapidly emerging Australian OTC market, thanks to our innovative product and registration strategy.*

We are excited to collaborate with Aspen, one of Australia's largest and most successful pharmaceutical companies with an impressive track record in sales, marketing, manufacturing, and distribution.

Aspen's extensive sales force is unique in that it can reach both pharmacies and prescribing doctors, which will be instrumental in ensuring that Emyria's product has strong brand awareness and gains widespread adoption after registration."

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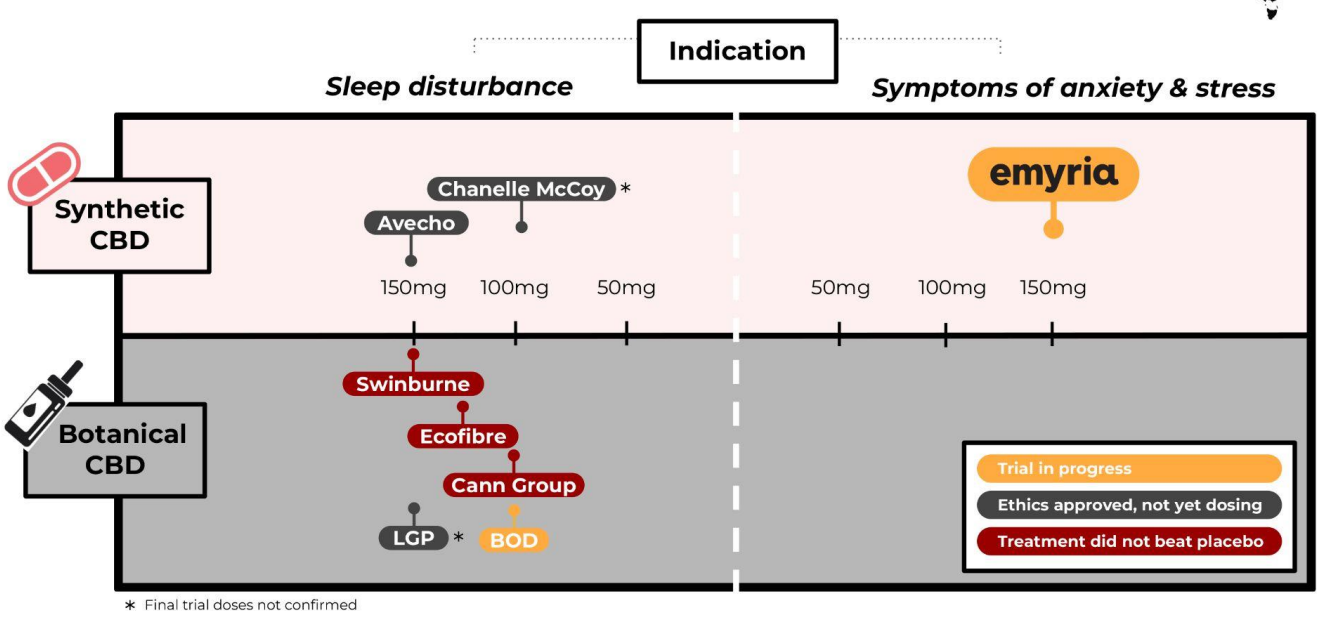
EMD-RX5 OVER-THE-COUNTER COMPETITIVE LANDSCAPE



Currently, the market for registered CBD medicine is dominated by Jazz Pharmaceuticals' Epidyolex oil, a prescription medication for rare seizure disorders that generates over AUD$1B in annual sales globally. [4]

While the TGA has allowed low dose CBD (<150mg/day) to be registered as an OTC medicine since December 2020, no CBD product has yet achieved this registration. [5]

Emyria's EMD-RX5, a proprietary formulation of Ultra-Pure CBD, has been developed as a potential over-the-counter CBD medication.

EMD-RX5 is based on insights from Emyria's unique Real-World Data gathered with over 8,000 patients prescribed pharmaceutical-grade cannabinoid medicines at their clinical service subsidiary, Emerald Clinics.

Notably, EMD-RX5 contains no THC or impurities, and requires less cost, energy, and water to produce than plant-based CBD products. In a head-to-head PK study EMD-RX5 demonstrated excellent bioavailability, safety, tolerability, and lower dose variability compared to Epidyolex oil.

Emyria's initial target indication is to treat the symptoms of mild anxiety and stress in patients with a chronic condition. **Anxiety and stress affect up to 15% of the adult population** [1] with a higher prevalence in patients with chronic disease, such as chronic pain which affects around 2.8 million adults in Australia [2]. Emyria's Real World Data suggests up to 50% of patients with Chronic Pain experience anxiety and stress symptoms. There is currently no OTC treatment for these symptoms and Emyria sees a significant opportunity for EMD-RX5 to address this unmet need in the OTC market.

1. https://www.aihw.gov.au/reports/burden-of-disease/abds-impact-and-causes-of-illness-and-death-in-aus/summary
2. AIHW "Chronic Pain In Australia" (published May 2020)
3. https://www.aspenpharma.com.au/about-aspen/
4. https://investor.jazzpharma.com/news-releases/news-release-details/jazz-pharmaceuticals-announces-full-year-and-fourth-quarter-2022
5. https://www.tga.gov.au/news/media-releases/over-counter-access-low-dose-cannabidiol

ABOUT EMYRIA AGREEMENT WITH ASPEN PHARMACARE AUSTRALIA

Under the agreement, Emyria will generally be paid a royalty between 5% to 10% of net sales based on annual net sales and gross profit targets. The 10% royalty applies when annual sales exceed $50M. In addition, Emyria will earn a total milestone payment of A$400,000 comprising two separate milestone payments of $200,000, which are satisfied upon the successful registration with the TGA and the successful launch of the product in market.

While the agreement contains binding commercial terms, the agreement is subject to the parties entering into a full form licensing agreement by 31 November 2023.

The initial term of the agreement is for 10 years and subject to Aspen entering into supply agreements with the capsules manufacturer and API supplier by 31 October 2023.

The agreement will terminate if the clinical trial fails to generate adequate data to support a TGA submission by 1 July 2024. Either party can terminate the agreement if the product is not registered within two years of submission to the TGA. The long-form agreement may contemplate nominal discounts for the Licensee, in the early stages, where Aspen Australia's net gross profit margin is less than a specified threshold.

The companies also commit to working together to explore the feasibility of local manufacturing, using Aspen's capabilities as well as new opportunities, indications and markets for EMD-RX5 in the OTC space.

ABOUT ASPEN PHARMACARE AUSTRALIA PTY LTD

Aspen Pharmacare Australia Pty Ltd (Aspen) is headquartered in Sydney, Australia and is 100% wholly owned subsidiary of Aspen Pharmacare Holdings. Aspen Australia employs ~600 people which includes a team of ~80 sales and marketing staff across its Prescription and Consumer OTC divisions.

ABOUT ASPEN PHARMACARE HOLDINGS PTY LTD

Aspen Pharmacare Holdings is a JSE listed (South Africa) global specialty and branded pharmaceutical company with a presence in both emerging and developed markets. Established over 170 years ago, it has more than 9 000 employees in over 50 countries and provides high quality, affordable medicines to patients in more than 115 countries. Aspen is headquartered in South Africa, with a market cap of ~$6B AUD.

Aspen Pharmacare Holdings operates 23 manufacturing facilities across 15 sites and holds international manufacturing approvals from some of the most stringent global regulatory agencies including, among others, the United States Food and Drug Administration, the Australian Therapeutic Goods Administration and the European Directorate for the Quality of Medicines.

UPCOMING MILESTONES

CLINICAL PROGRAMS

"direct-to-consumer"
Formulation optimisation (RX5) ✓
Phase 1 study done ✓
Phase 3 commencement ✓
Regulatory submission
Commercial strategy **Australia** ✓
Commercial strategy **Europe**
Commercial strategy **USA**

"prescription medicine"
Formulation optimisation (RX7) ✓
Phase 1
Pre-IND **(FDA)**
Pivotal trials

PRE-CLINICAL + THERAPY PROGRAMS

New Drug Discovery
Continuous creation & screening ✓
First patent family filed ✓
US-focused preclinical program ✓
Metabolic studies ✓
Lead selection
Phase 1 trials
Global commercial strategy

MDMA-assisted therapy
Protocol developed ✓
Clinical partnerships ✓
Real-World Data system ✓
MDMA supply secured ✓
Therapist training
First patient
Global commercial strategy

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.

This release has been approved by the Board of Emyria.

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.

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.

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