ASX Announcement

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Emyria executes pure CBD agreement with AltaSciences to accelerate FDA and TGA cannabinoid registration programs

Highlights:

- Emyria has contracted leading North American drug manufacturer, AltaSciences, to deliver a range of novel, synthetic cannabinoid-based medicines for Emyria's Australian and US drug registration program

- Major advantages of Emyria's novel, pure cannabinoid platform:
  - **Accelerated US FDA Registration** - By using pure, synthetic cannabinoid Active Pharmaceutical Ingredients (APIs), Australian clinical development and trials can also support US/FDA registration efforts, greatly accelerating timelines for FDA registration
  - **Ownership** - Emyria will retain 100% ownership, commercialisation rights and revenues for all Emyria-led cannabinoid programs
  - **Cost effective** - Synthetic CBD currently has a significantly lower cost compared to plant derived options, substantially improving affordability, patient access and providing Emyria with a cost competitive advantage

- AltaSciences is an award-winning contract drug manufacturer with over 1,000 employees and 7 locations across the US and Canada

- Emyria's leading drug registration program, EMD-003, will utilise this pure CBD platform and is aimed at delivering one of the first registered Schedule 3, over-the-counter cannabidiol (CBD) medicines

- EMD-003 drug registration timelines remain on track, with clinical trial material due to arrive in Q4, 2021

Emyria Limited (ASX: EMD) (Emyria or the Company), a data-backed drug development and care delivery company, has engaged AltaSciences to deliver a range of proprietary, synthetic cannabinoid-based capsules utilising a unique drug delivery approach. These capsules will become the foundation for Emyria's cannabinoid drug development programs targeting registration with the TGA and FDA, leading with the EMD-003 over-the-counter ('OTC') program.

The new capsules are being developed to meet both TGA and FDA quality standards and are likely to be much more cost effective than the previous supply options considered and will allow Emyria to retain 100% ownership of all commercialisation rights and revenues.

By selecting synthetic CBD, Emyria has ensured that its drug development programs, and Australian-based clinical trials, can also support the pursuit of FDA registration following TGA registration. There is no pharmacological difference in vitro in the antiproliferative, anti-inflammatory, or permeability effects of purified botanical CBD versus pure synthetic CBD [1]. Further, the development benefits and cost savings that synthetic drug material provides are substantial. The synthetic platform under development is expected to support multiple drug registration programs with the TGA and FDA.

Emyria's EMD-003 is a Schedule 3, low-dose cannabidiol drug registration program and will be the first to make use of the new pure synthetic dose form. EMD-003 is targeting the symptoms of psychological distress. *(See ASX release 07 Apr 21)*.

EMD-003 is on track to deliver one of the first successfully registered, over-the-counter CBD medicines in Australia. Emyria has already completed much of the preliminary registration work including:

- received feedback from the TGA regarding the target indication and the utility and importance of Emyria's Real-World Evidence (RWE) for drug registration
- filed patents supporting use of cannabinoids to treat the target indication
- developed the pivotal trial protocols
- secured independent clinical trial sites to support Emyria's patient recruitment for the pivotal trial
- engaged regulatory resources with prior, successful Schedule 3 registrations experience
- built an expert clinical advisory team to support the pivotal studies

Registration activities are covered with Emyria's current cash position.

Emyria's Managing Director, Dr. Michael Winlo, said: *"We are excited to be contracting AltaSciences to deliver a range of novel synthetic CBD medicines for our drug registration programs led by EMD-003.*

Emyria has been seeking a platform which can deliver a proprietary, cost effective and FDA-compliant cannabinoid medicine for some time. We have always been committed to pursuing registration opportunities with the FDA in the USA in parallel to our Australian programs as the US is the world's largest pharmaceutical market. The FDA is tightening rules on cannabinoid medicines and registration is required if reimbursement and product claims are targeted.

The novel platform we are advancing with AltaSciences has several key benefits for Emyria. First, all of our GMP cannabinoid products will also meet FDA specifications for purity and quality. This means the clinical trials and investment required to obtain TGA registrations can also support our FDA registration plans. This brings our US registration plans forward significantly.

Emyria will also have complete ownership over our Australian and US drug development programs, reducing our reliance on third-parties and allowing us to move rapidly towards TGA registration and sales in pharmacies where there is already a great deal of patient and commercial interest.

Further, our pure API can be supplied to patients far more cost effectively. As patients will have to pay out-of-pocket for an over-the-counter CBD, it is essential to register a product that is effective, affordable and reliable to achieve large-scale uptake and sales. Currently, patients are required to spend more than $400 a month, out-of-pocket, which is not sustainable.

For EMD-003, we believe our clinical data, drug development expertise and patent portfolio, when combined with a unique and low-cost dose form, will allow us to become one of the first successfully registered and affordable Schedule 3 cannabinoid medicines in Australia. We look forward to providing more updates to the market about our global registration plans in the coming weeks."

AltaSciences
AltaSciences is an award-winning contract drug manufacturer with over 1,000 employees and 7 locations across the US and Canada. AltaSciences will manufacture under contract by Emyria.

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

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References:

[1] The Pharmacological Effects of Plant-Derived versus Synthetic Cannabidiol in Human Cell Lines (https://doi.org/10.1159/000517120)

About Emyria (www.emyria.com)

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

About AltaSciences (www.altasciences.com)

Altasciences is a forward-thinking, mid-sized contract research organization offering pharmaceutical and biotechnology companies a proven, flexible approach to preclinical and clinical pharmacology studies, including formulation, manufacturing, and analytical services. Altasciences has been partnering with sponsors to help support educated, faster,and more complete early drug development decisions.

Altasciences' integrated, full-service solutions include preclinical safety testing, clinical pharmacology and proof of concept, bioanalysis, program management, medical writing, biostatistics, clinical monitoring, and data management, all customizable to specific sponsor requirements. Altasciences helps sponsors get better drugs to the people who need them, faster.

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.