

AusCann releases hard-shell capsules to clinical evaluation and commences a fast track path to market

Highlights

- AusCann has released its cannabinoid-based hard-shell capsules for clinical evaluation.
- Successful manufacturing, testing and release of a commercial sized batch in Australia, is a critical milestone on AusCann's road to sales.
- AusCann's target is to have the hard-shell capsules commercially available for physicians to prescribe in Australia during the first half of CY 2020.

18 December 2019 – Leading medicinal cannabis pharmaceutical company **AusCann Group Holdings Limited** (ASX: AC8) (AusCann or 'the Company') is pleased to announce it has completed manufacturing and testing of its proprietary cannabinoid-based hard-shell capsules and released the hard-shell capsules for clinical evaluation. The Company is working to develop a commercially focused, short clinical evaluation. AusCann's solid-fill capsule formulation is a unique presentation for cannabinoid medicines, and the clinical evaluation goal is to provide key exposure information to inform dose selection. The Company will inform the market once the clinical evaluation commences.

The hard-shell capsules were tested according to standardised validated tests used across the pharmaceutical industry to ensure product quality prior to release of products to market. The hard-shell capsules were tested and found to meet all applicable pre-defined criteria set by the Australian Therapeutic Goods Administration (TGA), relevant International Pharmacopoeial standards and AusCann's quality assurance and control procedures.

The release of the capsules validates AusCann as a commercial producer of reliable, stable and standardised pharmaceutical products:

- **Reliable:** Consistently producing dose-controlled capsules which enable controlled dose titrations and informed monitoring of health outcomes. The test results validate dose reliability for every capsule, assuring that each dose is true to label.
- **Stable:** Since cannabinoids tend to degrade over time when not adequately protected, AusCann products were designed to ensure that the capsules perform consistently throughout the shelf life of the product. The product design and testing completed confirms the hard-shell capsules' unique formulation will remain stable up to the expiry date of the product.
- **Standardised:** AusCann's products comply with validated quality control standards used internationally to ensure quality of pharmaceutical products prescribed by doctors.

An accelerated path to commercialisation – following all positive test results, AusCann will now progress with an accelerated path to commercialisation.

AusCann will supply products to physicians where approved under the Therapeutic Goods Administration Special Access Scheme and Authorised Prescriber Scheme. These

programs are based in Australia. AusCann is targeting hard-shell capsules availability for patients in Australia during the first half of CY 2020.

AusCann CEO, Mr Ido Kanyon said the release of the hard-shell capsules on a commercial scale is an important milestone on the Company's accelerated road to sales.

"AusCann had the vision to provide patients and healthcare professionals with a high-quality pharmaceutical product which addresses patients' unmet needs. AusCann's manufacturing, operational processes and test results are up to global pharmaceutical standards which is great news for patients, healthcare professionals and AusCann's investors. Now with this stage of our R&D program complete, we are accelerating our path toward commercialisation with full confidence in our ability to consistently provide reliable, stable and standardised pharmaceutical products which address unmet medical needs."

"AusCann is on track for a timely delivery of all its strategic priorities. The first was to finalise the production, testing and packaging of AusCann's pharmaceutical cannabinoid-based products for a release to clinical evaluation by the end of 2019. This has been successfully completed on time."

"We remain focused on making AusCann's capsules available for prescription to patients in Australia during the first half of 2020. Our goal is to provide high-quality medicine and to obtain detailed, data-driven evaluations regarding the outcomes of AusCann's pharmaceutical treatment. These results will build the clinical evidence supporting the unique benefits of AusCann's capsules necessary to open a large market for the Company."

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This ASX announcement was authorised for release by the AusCann Group Holdings Board.

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ABOUT AUSCANN

AusCann Group Holdings Limited (ASX:AC8) is an Australian-based pharmaceutical company focused on the development, production, and distribution of cannabinoid-based medicines within Australia and internationally. AusCann transforms the way Medicinal Cannabis is dispensed today by making standardised dose-controlled cannabinoid-based pharmaceutical products and clinical evidence accessible to patients, physicians and healthcare providers. AusCann enables physicians to treat their patients with a reliable, stable and standardised cannabinoid-based pharmaceutical product, monitor treatment results and adjust treatment algorithms using a portfolio of products and formulations.