**ASX Announcement**
3 December 2025

# US and European Patent Allowances Received for Avecho's Proprietary CBD Soft-Gel Formulation

**Highlights:**

- Patent applications allowed in the US and Europe covering Avecho's proprietary CBD TPM® soft-gel capsule, currently in Phase III clinical development for insomnia.
- Coverage extends to formulations incorporating cannabinoids beyond CBD, supporting future non-core commercialisation opportunities.
- Grant of patents on the allowed applications expected by the end of FY26.
- Once granted, patents will protect the CBD TPM® soft-gel capsule in the US and Europe until at least 2040.

**Melbourne, Australia, 3 December 2025:** Avecho Biotechnology Limited (ASX: AVE) ("Avecho" or "the Company") is pleased to announce that both the United States Patent and Trademark Office (USPTO) and the European Patent Office (EPO) have allowed the Company's patent applications relating to its proprietary cannabidiol (CBD) TPM® soft-gel capsule, designed to enhance the absorption of CBD.

The US and European applications, titled "Oral cannabinoid formulation comprising tocopheryl phosphates and long chain triglycerides or long chain fatty acids", strengthen Avecho's intellectual property position around its oral cannabinoid delivery technology in two major global markets. With all substantive examination hurdles now passed, the Company expects formal grant of the patents by the end of FY26.

Once granted, the patents will protect the novel combination of Tocopheryl Phosphate Mixture (TPM), cannabinoid, and lipid that forms the basis of Avecho's CBD soft-gel capsule until at least 2040. TPM, a derivative of Vitamin E, has been shown to significantly improve the solubility, stability, and absorption of active pharmaceutical ingredients, including cannabinoids.

**Avecho CEO, Dr Paul Gavin, said**: "Allowance of these applications in both Europe and the United States marks an important milestone for Avecho. It expands protection of our CBD TPM soft-gel capsule across two of the world's largest pharmaceutical markets. As we progress our pivotal Phase III trial, these allowances strengthen the foundation for future regulatory submissions and commercial discussions, while further validating our leadership in cannabinoid formulation technology."

Avecho is currently conducting a pivotal, multi-centre, randomised, double-blind, placebo-controlled Phase III clinical trial evaluating the efficacy and safety of its CBD TPM soft-gel capsule for the treatment of insomnia. The study—the largest global trial of cannabidiol for insomnia—was designed in consultation with international sleep and regulatory experts to meet requirements of the Therapeutic Goods Administration (TGA), US Food and Drug Administration (FDA), and European Medicines Agency (EMA). A planned interim analysis of the first ~210 patients is expected in H1 2026.

A positive outcome from this trial is anticipated to support a planned submission to the TGA for registration of the CBD TPM soft-gel capsule for the management of insomnia. In Australia, regulatory changes implemented in 2020 allow low-dose CBD products to be supplied over the counter through pharmacies once approved, presenting a potential first-mover opportunity for Avecho in a market projected to exceed US$125 million annually[1].

[1] Fresh Leaf Analytics, Australian Medicinal Cannabis Market, H1 2021.

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This announcement has been authorised by the Board of Directors of Avecho Biotechnology Limited.

**About Avecho**
Avecho Biotechnology Limited develops and commercialises innovative Human and Animal Health products using its proprietary drug delivery system called Tocopheryl Phosphate Mixture (TPM®). TPM is derived from Vitamin E using unique, proprietary and patented processes and is proven to enhance the solubility and oral, dermal and transdermal absorption of drugs and nutrients.

Avecho's lead asset is a proprietary cannabidiol ("CBD") TPM soft-gel capsule demonstrated to increase CBD absorption. The CBD soft-gel capsule is currently undergoing Phase III clinical development for the treatment of insomnia.

See more here - avecho.com.au

**About Insomnia**
Insomnia is a sleep disorder defined as dissatisfaction with sleep quantity or quality associated with difficulty initiating sleep, difficulty maintaining sleep and the inability to return to sleep on awakening. It can manifest as a primary indication or be symptom of other disorders, including anxiety and depression. Chronic insomnia is the most prevalent manifestation, characterised by insomnia symptoms occurring at least three nights per week and for at least three months. Consequences of insomnia include daytime sleepiness, poor memory function, decline in concentration with negative impacts on social and work activities. Approximately 10-30% of the global population have symptoms of insomnia, with 10-15% classified as chronic[2]. Based on the current global population, up to 237M people are affected by insomnia, with the sleep economy and sleep aids market estimated to reach US$950Bn by 2032[3]. In Australia, as many as ~60% of the population have at least some symptoms of insomnia with a total cost to the Australian economy estimated to be A$19.1 billion[4]. In August 2023, the Australian Government issued a statement indicating that sleep health should be considered a national priority as important as fitness and nutrition[5].

**About Avecho's Phase III Trial Program**
The Company is currently conducting a pivotal (Phase III), multi-centre, randomized, double-blind, placebo-controlled clinical trial evaluating the efficacy and safety of CBD TPM soft-gel capsules in adults for use in the reduction of insomnia severity. The trial is the largest of its kind testing cannabidiol, taking place at multiple sites around Australia. Aided by advice from international sleep and regulatory experts, the trial has been designed to meet the requirements of the Australian Therapeutic Goods Administration ("TGA"), US Food and Drug Agency and the European Medicines Agency. Trial Participants will be randomly assigned to one of three groups to receive nightly doses of either 75mg or 150mg of CBD, or a placebo for eight weeks. Participants will use validated questionnaires and daily sleep diaries over the course of the study to record the duration and quality of their sleep.

[2] https://www.thegoodbody.com/insomnia-statistics/
[3] https://finance.yahoo.com/news/sleep-economy-sleep-aids-market-133100851.html
[4] https://www.deloitte.com/au/en/services/economics/analysis/rise-try-to-shine.html
[5] https://www.health.gov.au/sites/default/files/2023-08/bedtime-reading-inquiry-into-sleep-health-awareness-in-australia.pdf

Further information about the study can be found at ClinicalTrials.gov (Study Identifier: NCT05840822).

A successful Phase III trial is Avecho's final clinical step in support of a submission to the TGA for pharmaceutical registration of the CBD TPM soft-gel capsule for the management of insomnia. This opportunity is particularly significant in Australia, where regulatory changes in 2020 allow for over-the-counter sales of CBD products direct from pharmacy without a prescription, provided they gain appropriate approvals. Avecho has an opportunity to be the first in this area as no other Phase III CBD trials in Australia have succeeded. Initial projections estimated the Australian over-the-counter CBD market would grow to over US$125M per annum[6].

**Forward-Looking Statements**

Certain statements in this announcement are forward looking statements. Forward-looking statements can generally be identified by the use of words such as "anticipate", "estimate", "expect", "project", "intend", "plan", "believe", "target", "may", "assume" and words of similar import. These forward-looking statements speak only as at the date of this announcement. These statements are based on current expectations and beliefs and, by their nature, are subject to a number of known and unknown risks and uncertainties that could cause the actual results, performances and achievements to differ materially from any expected future results, performance or achievements expressed or implied by such forward looking statements.

No representation, warranty or assurance (express or implied) is given or made by Avecho that the forward-looking statements contained in this announcement are accurate, complete, reliable or adequate or that they will be achieved or prove to be correct. Except for any statutory liability which cannot be excluded, Avecho and its respective officers, employees and advisers expressly disclaim any responsibility for the accuracy or completeness of the forward-looking statements and exclude all liability whatsoever (including negligence) for any direct or indirect loss or damage which may be suffered by any person as a consequence of any information in this announcement or any error or omission therefrom.

Subject to any continuing obligation under applicable law or relevant listing rules of the ASX, Avecho disclaims any obligation or undertaking to disseminate any updates or revisions to any forward-looking statements in these materials to reflect any change in expectations in relation to any forward-looking statements or any change in events, conditions or circumstances on which any statement is based. Nothing in these materials shall under any circumstances create an implication that there has been no change in the affairs of Avecho since the date of the announcement.

Avecho's major projects include delivering TPM enhanced injectable, oral and topical products for the human health market, including the recently announced application of TPM to cannabinoids. The Company is also developing TPM® to enhance feed efficiency and health of livestock.



[6] Fresh Leaf Analytics, Australian Medicinal Cannabis Market, H1 2021