

ASX Announcement

28 March 2025

Avecho receives US\$3M upfront payment from Sandoz AG for license to commercialise CBD for insomnia in Australia**Highlights:**

- Avecho has received the US\$3M (~A\$4.79M¹) licensing fee from Sandoz AG for the commercial rights to Avecho's CBD capsule for insomnia in Australia
- Avecho is eligible for subsequent milestone and royalty payments:
 - US\$16M in development milestones prior to commercial sales
 - Tiered royalties ranging from 14% to 19% on net sales
 - Sandoz to purchase the product from Avecho for commercial sale
- Avecho retains the rights to commercialise the product in all other territories, with Sandoz granted a right of first refusal to exceed any commercial offers Avecho receives
- Market for over-the-counter cannabidiol registered in Australia forecast to grow to >US\$125M per annum²

Melbourne, Australia, 28 March 2025: Avecho Biotechnology Limited (ASX: AVE) ("Avecho" or the "Company") is pleased to announce that it has received the initial US\$3M licensing fee from Sandoz AG ("Sandoz") as part of the recently signed licensing agreement for the commercial rights to Avecho's proprietary cannabidiol ("CBD") product in Australia. Under the terms of the agreement, Sandoz has been granted exclusive commercial rights for Avecho's Phase III CBD capsule for insomnia in Australia for a period of ten years. Avecho will retain the rights to commercialize the product in all other territories, with Sandoz holding a first right of refusal for these markets.

Avecho's CBD capsule aims to be the first pharmaceutical CBD product registered with the Therapeutic Goods Administration ("TGA") as an over-the-counter medicine in Australia. Market forecasts suggest the product could generate annual sales exceeding US\$125M in the Australian market². This agreement marks an important milestone for Avecho as it continues to expand its commercial opportunities.

Avecho will continue to fund and oversee the ongoing Phase III clinical trial. Upon successful completion, Avecho and Sandoz will collaborate to secure TGA regulatory approval. Sandoz will purchase finished product from Avecho and assume responsibility for the product's commercialisation, including marketing and distribution in Australia. Avecho is eligible for development milestone payments totalling US\$16M prior to commercialisation and will receive tiered royalties ranging from 14% to 19% on net sales once on market.

Avecho CEO, Dr Paul Gavin, said: *"The upfront licensing fee from Sandoz strengthens our financial position, providing the necessary support to accelerate ongoing research and commercial activities. With ample capital to complete our pivotal Phase III trial through to the interim analysis, our primary focus is to advance the study to this key inflection point as swiftly as possible".*

For enquiries, please contact

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¹ Based on RBA exchange rate of 1 USD = 1.59 AUD as at 27 March 2025.

² Fresh Leaf Analytics, Australian Medicinal Cannabis Market, H1 2021.



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

About Sandoz

Sandoz is the global leader in generic and biosimilar medicines, with a growth strategy driven by its Purpose: pioneering access for patients. More than 20,000 people of 100 nationalities work together to ensure 800 million patient treatments are provided by Sandoz, generating substantial global healthcare savings and an even larger social impact. Its leading portfolio of approximately 1,500 products addresses diseases from the common cold to cancer. Headquartered in Basel, Switzerland, Sandoz traces its heritage back to 1886. Its history of breakthroughs includes Calcium Sandoz in 1929, the world's first oral penicillin in 1951, and the world's first biosimilar in 2006. In 2023, Sandoz recorded net sales of USD 9.6 billion.

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 chronic³. 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 2032⁴. 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 billion⁵. In August 2023, the Australian Government issued a statement indicating that sleep health should be considered a national priority as important as fitness and nutrition⁶.

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.

³ <https://www.thegoodbody.com/insomnia-statistics/>

⁴ <https://finance.yahoo.com/news/sleep-economy-sleep-aids-market-133100851.html>

⁵ <https://www.deloitte.com/au/en/services/economics/analysis/rise-try-to-shine.html>

⁶ <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 annum².

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.