ASX Announcement
3 March 2025

Avecho and Sandoz enter exclusive license and development agreement to commercialise CBD for insomnia in Australia

Highlights:

- Avecho and Sandoz sign an exclusive ten-year development and license agreement ("Agreement") for Avecho's pharmaceutical cannabidiol capsule for insomnia in Australia
- Avecho to receive upfront, milestone and royalty payments:
  - US$3M (~A$4.8M[1]) in upfront payment
  - 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 annum[2]
- CEO Dr Paul Gavin will discuss this announcement further during an investor webinar to be held at 11.00am (AEDT) on Tuesday 4 March 2025 – click here to register

Melbourne, Australia, 3 March 2025: Avecho Biotechnology Limited (ASX: AVE) ("Avecho" or the "Company") today announced it has signed an exclusive ten-year development and licensing agreement with Sandoz Group AG ("Sandoz") for the commercial rights to Avecho's Phase III cannabidiol ("CBD") capsule for insomnia in Australia. Avecho retains the rights to commercialise the product in all other territories, with Sandoz granted 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, which market forecasts predict could generate sales surpassing US$125M per annum in Australia[2].

Sandoz has agreed to an upfront licensing fee of US$3M (approx. A$4.8M[1]) for the exclusive commercial rights to the CBD product for insomnia in Australia. 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: "*We are excited to announce this partnership with Sandoz, which underscores the commercial potential of Avecho's drug delivery platform and our shared commitment to deliver innovative insomnia treatments. Nearly 9.5 million Australians experience symptoms of insomnia with approximately 3.6 million of those considered chronic[3]. Sandoz's extensive reach and expertise in the Australian market will ensures our products are widely accessible to insomnia patients across Australia. This partnership provides Avecho with a strong commercial foundation for success.*"

[1] Based on RBA exchange rate of 1 USD = 1.61 AUD as at 28th February 2025.
[2] Fresh Leaf Analytics, Australian Medicinal Cannabis Market, H1 2021.
[3] The societal and economic burden of insomnia in adults: An international study, RAND, 2023.

The Agreement as an initial term of 10 years, with automatic extensions for two further renewal terms of two years each, unless terminated by agreement between both parties. The Company also confirms that the Agreement is otherwise subject to standard terms and conditions typical of a contract of this nature.

Investor webinar
Avecho will hold an investor webinar for shareholders and all other interested parties to provide more detail on this major milestone for the company.

CEO, Dr Paul Gavin, will present at 11.00am (AEDT) on Tuesday 4 March 2025.

Register to attend the presentation at the following link:
https://us02web.zoom.us/webinar/register/WN_t4VmfT8RTX-0FexBBLJ_6Q

A recording will be available at the above link shortly after the conclusion of the live session, and the replay will also be available via the Company's website and social media channels.

Questions can be submitted on the day or sent in advance to matt@nwrcommunications.com.au.

For enquiries, please contact
Dr Paul Gavin
Chief Executive Officer
Avecho Biotechnology Limited
+61 3 9002 5000

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 chronic[4]. 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[5]. 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[6]. 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[7].

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.

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[2].

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.

4 https://www.thegoodbody.com/insomnia-statistics/

5 https://finance.yahoo.com/news/sleep-economy-sleep-aids-market-133100851.html

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

7 https://www.health.gov.au/sites/default/files/2023-08/bedtime-reading-inquiry-into-sleep-health-awareness-in-australia.pdf

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.