ASX Announcement
4 March 2025

Avecho Investor Webinar and Presentation

Melbourne, Australia, 4 March 2025: Avecho Biotechnology Limited (ASX: AVE) ("Avecho" or the "Company") invites Shareholders to attend its investor webinar to be held today, Tuesday 4 March 2025, at 11.00am (AEDT), following the licensing agreement with Sandoz Group AG ("Sandoz").

Investor webinar

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. Participants attending the Webinar may also submit questions during the session.

For enquiries, please contact

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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[1]. 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[2]. 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[3]. 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[4].

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.

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

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

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

4 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.



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Licensing Webinar

March 2025

www.avecho.com.au | ASX:AVE

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Safe Harbour Statement

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This presentation, and any representations made before, during or after the presentation, may include forward-looking statements that are inherently subject to risks and uncertainties. These statements relate to, but are not limited to: (1) the safety or efficacy of, or potential applications for, Avecho's TPM® platform technology; (2) the strength of Avecho's intellectual property; (3) the timelines for Avecho's clinical trials and regulatory processes for its different products; (4) the scalability and efficiency of manufacturing processes; (5) revenue projections, market share expectations, share price expectations and capital requirements.

Actual results may differ from the expectations expressed in these forward-looking statements, and the differences may be material (whether positive or negative). The risks that may cause Avecho's actual results, performance or achievements to be materially different from those expressed or implied by such forward-looking statements, include but are not limited to: (1) risks inherent in the development, approval and commercialization of potential products; (2) uncertainty of clinical trial results or regulatory approvals or clearances; (3) changes to market trends or government laws or regulations; (4) the potential need for future capital; (5) dependence upon collaborators; and (6) protection of intellectual property rights, among others. Accordingly, you should not place undue reliance on these forward-looking statements.

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Summary

Phase 3 Opportunity



Drug Product

- TPM-enhanced cannabidiol (CBD) capsule for insomnia
- In a pivotal Phase III clinical trial

Insomnia indication

- Difficulty falling or staying asleep
- Affects 10-30% of the population, with 10-15% classified as chronic

Market Opportunity

- Unique Australian OTC opportunity: Market potential >$US 125M per annum
- 3.6M Australians with chronic insomnia; 9.5M with symptoms of insomnia
- 237M people worldwide suffering from insomnia

Commercial Validation

- Commercial licensing deal with Sandoz for Australia
- Attractive terms: substantial revenue upon commercialization

Upcoming Milestones

- Interim Analysis
- Potential licensing deals in new territories

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Ideal partner for Avecho's CBD insomnia capsule



Large pharmaceutical company
Financial stability



R&D Capabilities
Experience in the clinical development of new medications



Regulatory expertise
Strong understanding of Australian TGA regulatory requirements



Significant interest in the Australian market
Understand/appreciate the significant TGA OTC opportunity



Robust distribution network
Ensure product reaches market efficiently through Australian Pharmacy



Global reach
Presence all around the world



Strong Track Record and Reputation
Reputation Matters

SANDOZ

Swiss-based multinational pharmaceutical company spun out of Novartis
(Market Cap ~$US 20Bn)

Global presence with a portfolio of ~1,500 approved medicines and annual revenues >$US 10Bn

Focus on driving access to make a real difference for patients worldwide[1]

Purpose

Pioneering access for patients

Vision

To be the world's leading and most valued biosimilars and generics company

Estimated Global Impact

>800 million*
Patient treatments provided annually

>$US 18Bn savings
Generated annually in EU & US ^

~$US 400Bn#
Estimated annual social impact of key medicines

1. Sandoz Integrated Annual Report 2023. Available from: https://prod.cms.sandoz.com/sites/spare53_sandoz_com/files/Media%20Documents/2023-Integrated-Annual-Report.pdf. P.3365. (accessed April 2024)

* Calculated based on volumes sold, the daily dose as defined by the World Health Organisation, the treatment duration and certain adjustments from internal medical experts

^. AAM as data source for US healthcare system savings; IQVIA Midas data source for EU healthcare system savings

#. Based on 2023 WifOR Institute analysis

SANDOZ



Strong Australian presence to efficiently and effectively execute

Australia's 2nd largest generics and biosimilars company with a dedicated team focussed on driving OTC medicines

Nationwide presence and strong partnerships with major pharmacy banner groups

Robust distribution network already in place, with the capability to supply every pharmacy nationally

47 person strong face-to-face sales team, nationally located to cover the vast Australian geography

Avecho | SANDOZ Partnership



Key Terms

Sandoz acquires exclusive rights to Avecho's pharmaceutical cannabidiol capsule for insomnia in Australia.

Avecho to receive upfront, milestone and royalty payments:

$US 3M
(~A$4.8M) in upfront payment upon signing

$US 16M
in development milestones prior to commercial sales

Tiered royalties ranging from
14% to 19%
on net sales

Avecho responsible for the completion of the Phase III trial and supporting development activities

Sandoz responsible for the sales, marketing and commercialization of the product in Australia.

- Sandoz to purchase the product from Avecho for commercial sale

Sandoz granted a right of first refusal for commercial rights to territories outside Australia and/or new clinical indications for the CBD capsule.

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Forecast market size

Insomnia is broadly defined as difficulty initiating or maintaining sleep

It affects 10-30% of the population, with 10-15% of the population classified as chronic[1,2]

9.5M
people in Australia experience symptoms of insomnia

3.6M
people in Australia classified as chronic insomniacs

Initial forecasts for OTC CBD in Australia are

>$US 125M per year[3]

1. https://www.deloitte.com/au/en/services/economics/analysis/rise-try-to-shine.html
2. The societal and economic burden of insomnia in adults: An international study, RAND, 2023
3. Fresh Leaf Analytics, Australian Medicinal Cannabis Market, H1 2021



Globally

Up to **237M** people are affected[4]

Insomnia costs the US economy **$US 63Bn** each year

Big Business: The sleep economy and sleep aids market estimated to reach **US$ 950Bn** by 2032[5]

4. https://www.thegoodbody.com/insomnia-statistics/
5. https://finance.yahoo.com/news/sleep-economy-sleep-aids-market-133100851.html

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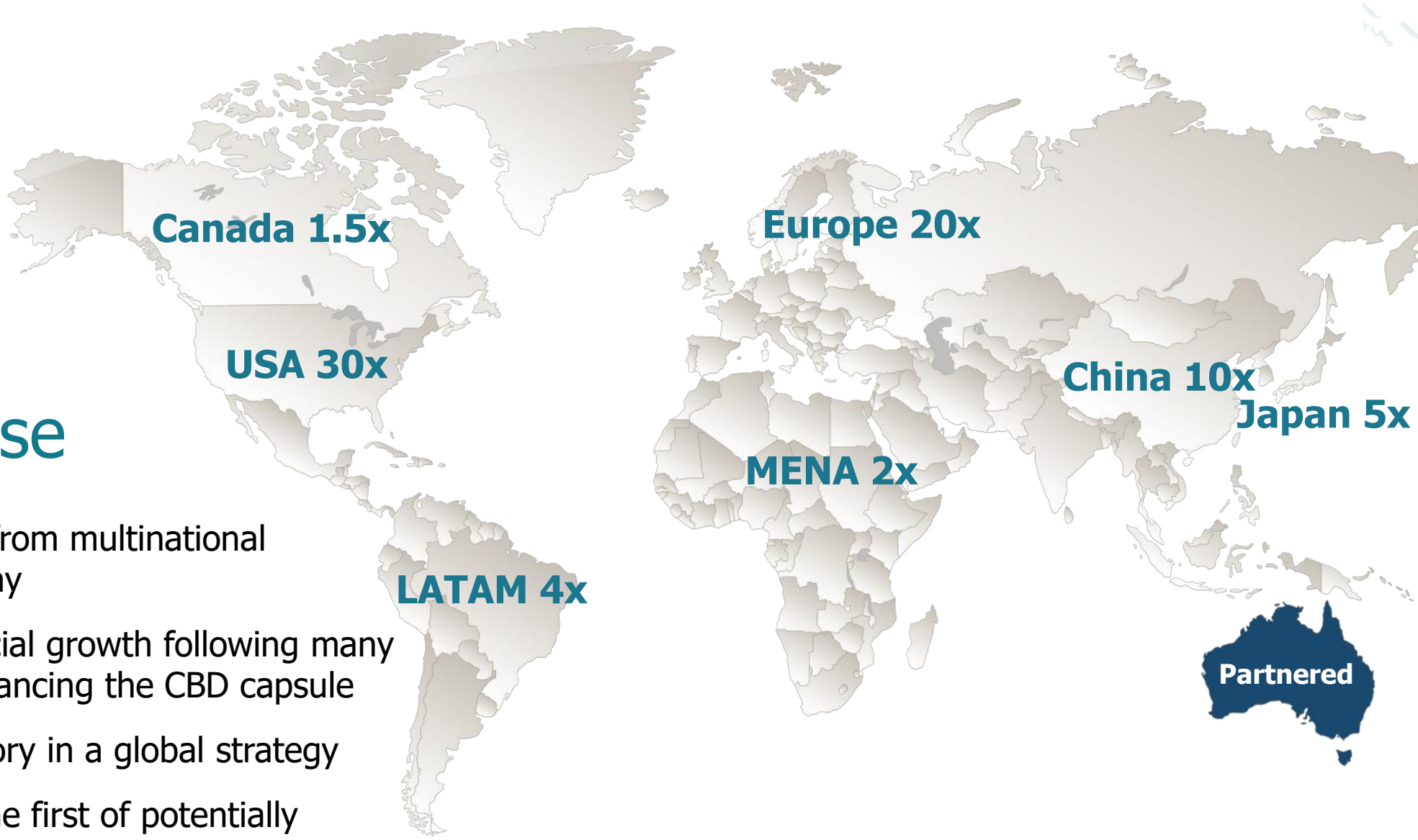
Commercial Growth Phase



- Commercial validation from multinational pharmaceutical company
- New phase of commercial growth following many years of hard work advancing the CBD capsule
- Australia the first territory in a global strategy
- Licensing deal marks the first of potentially several agreements globally

Australian deal the benchmark for further territories

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Phase III Interim Analysis

Next Major Milestone

⟵ 8-week treatment period ⟶

Treatment A – Placebo before bed

Treatment B – 75 mg CBD before bed

Treatment C – 150 mg CBD before bed

Assessments include

- Daily sleep diary to record nightly sleep.
- Sleep questionnaire every two weeks.
- Secondary endpoints related to anxiety

Interim Analysis

- As of December 2024, 70 patients have received study medication
- Interim analysis to be conducted after 219 patients
- Used to confirm effect of medication and calculate remaining patient numbers
- Major Phase III milestone
- Remaining patients required for interim analysis to be completed in 2025

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Increasing shareholder value

Dimerix Case Study

Dimerix (ASX:DXB) are in a Phase III clinical trial for Focal Segmental Glomeruloscelosis (FSGS)

Orphan indication (<200,000 patients in the US)

1. **Phase III trial underway**: ~$26M market cap
2. **First licensing deal** (ANZ, EU, UK, Canada): ~$89M market cap (Increased 3.42x)
3. **Positive interim analysis**: ~$130M market cap (Further increased 1.46x)
4. **Capital raise**: ~$180M market cap (Further increased 1.38x)
5. **Second licensing deal** (MENA): ~$336M market cap (Further increased 1.86x)

Market cap increased **12.92x within 12 months**



Avecho entering similar window of opportunity on our Phase III trial

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The year in front of us



Partner

Complete

- Sign commercial partner for CBD insomnia product in Australia

Complete Trial

- Complete Phase III trial to interim analysis
  - Discuss results with TGA. Study completed?
  - Dosing further patients to completion

Partner

- Partner discussions for CBD product in further territories

Partnerships for further cannabinoid products

TGA

- Commence build of TGA submission dossier

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Questions Welcome

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