Avecho

BELL POTTER HEALTHCARE CONFERENCE

NOVEMBER 2024

www.avecho.com.au | ASX:AVE

SAFE HARBOUR STATEMENT

AVECHO BIOTECHNOLOGY

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.

CLEAR STRATEGIC FOCUS

1. Complete pivotal Phase III clinical trial for CBD capsule containing TPM® technology

2. License this and other TPM cannabinoid products into global markets

COMPANY SNAPSHOT

AVE Corporate Summary	
Total shares	3.17 Bn
Total options[1]	2.37 Bn
Cash (end Q3 2024)	A$3.6 M
MCAP[2]	A$9.51 M

[1] Various exercise price and expiry dates
[2] As of COB 14th November 2024

Management Team

Dr Paul Gavin
Chief Executive Officer

Dr Roksan Libinaki
Chief Operating Officer

Melanie Leydin
Chief Financial Officer
& Co. Sec

Board

Dr Greg Collier
Chairman

Dr Ross Murdoch
Non-Executive Director

Matt McNamara
Non-Executive Director

Kathy Connell
Non-Executive Director

INSOMNIA HAS BECOME A MAJOR PROBLEM WORLDWIDE

Insomnia is broadly defined as difficulty initiating or maintaining sleep.

Insomnia affects 10-30% of the population, with 10-15% of the population classified as chronic.

Insomnia can be a symptom of a range of other disorders, particularly mental health and psychiatric disorders, and can contribute to their onset or exacerbation.

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

PHARMACEUTICAL CANNABIDIOL

Cannabidiol (CBD) is the major non-psychoactive component of medicinal cannabis

Only one pharmaceutical CBD product is approved by the FDA (Epidiolex®)[1]

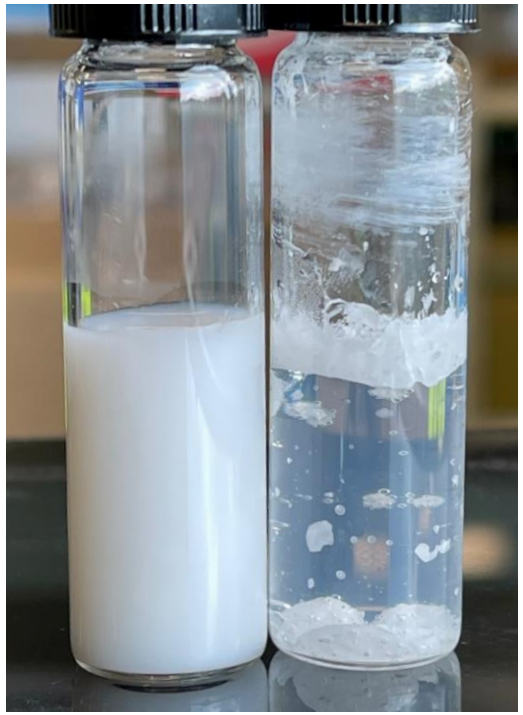
- Epidiolex was developed by GW Pharma
- Approved for rare childhood epilepsy conditions[2] – rarely prescribed
- GW Pharma was acquired for **$7.2Bn USD** by Jazz Pharma (2021) to obtain Epidiolex[3]
- One of the **side effects of Epidiolex is sleepiness**

No pharmaceutical CBD products are approved for sleep, but insomnia remains one of the most prevalent indications targeted globally by medical cannabis and consumer CBD products[4]

Sources:
1. https://www.epidiolex.com/
2. https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuana-treat-rare-severe-forms
3. https://investor.jazzpharma.com/news-releases/news-release-details/jazz-pharmaceuticals-acquire-gw-pharmaceuticals-plc-creating
4. Suraev, A.S., et al.. Cannabinoid therapies in the management of sleep disorders: A systematic review of preclinical and clinical studies. Sleep Medicine Reviews 2020b (53); 101339

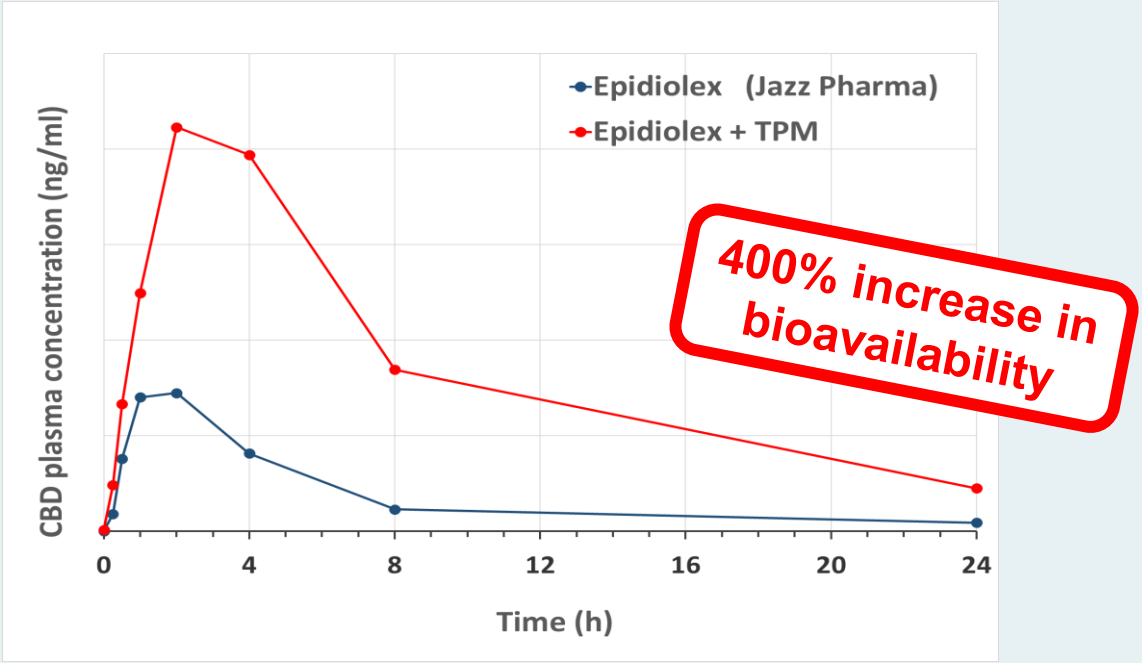
AVECHO'S TPM INCREASES CBD ABSORPTION

CBD Solubility



With TPM Without TPM

Avecho's TPM increases oral CBD absorption



- Single oral dose of Epidiolex (FDA approved CBD oil) or Epidiolex + TPM administered to dogs
- Blood collected over time and the amount of CBD in blood quantified

UNIQUE AUSTRALIAN TGA OPPORTUNITY

Australia's Therapeutic Goods Association (TGA) now allows oral CBD products to be registered as over-the-counter (OTC) medicines[1] for indications such as insomnia

OTC medicines are available direct from a pharmacist without a prescription, a significant commercial advantage

Australians spend **$5B per year** on OTC medicines[2]

The TGA has confirmed that insomnia is an appropriate indication for an OTC CBD product

Avecho met with the TGA in February to discuss the Phase III protocol and future submission plans. The TGA had no requested changes.

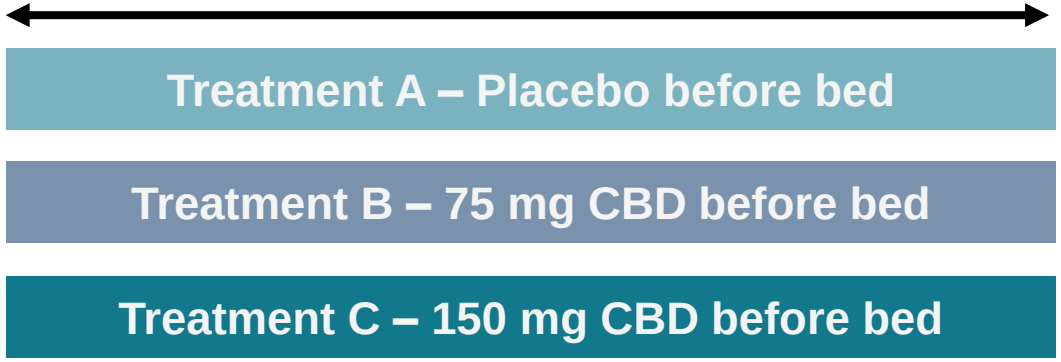
Avecho is well placed to be one of the first to achieve OTC TGA registration

Sources:
1. https://www.tga.gov.au/news/media-releases/over-counter-access-low-dose-cannabidiol
2. Medicines in the health system, Australian Institute of Health and Welfare (2022)

PHASE III STUDY DESIGN

Based upon study design from FDA approved insomnia medications

8 week treatment period



Assessments include;

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

Avecho's Phase III insomnia trial has been designed to maximise the chance of success. Compared to recent studies, Avecho's trial uses;

- **The maximum dose (150mg)**
- **Larger patient numbers (519 patients)**
- **Higher insomnia scores required for inclusion**
- **Longer dosing period (8 weeks)**
- **An interim analysis (after 219 patients) to calculate required patient numbers**
- **Methods to minimise the placebo effect**

PHASE III UNDER WAY

Initial Trial Targets

- **519** patients in total
- **~219** patients complete dosing to interim analysis

- Trial sites used in Melbourne, Perth, Brisbane, Western Sydney and Central Coast, NSW.
- 1st patient dosed in April: all sites up and running by July
- 70 patients on study medication
- Further patients being screened by sites for eligibility
- Plans in place to increase recruitment

Trial sites around Australia

COMPETITIVE LANDSCAPE

Four Australian companies pursued Phase IIb/III clinicals in insomnia targeting TGA registration - three failed

Avecho is the last company in active clinical development

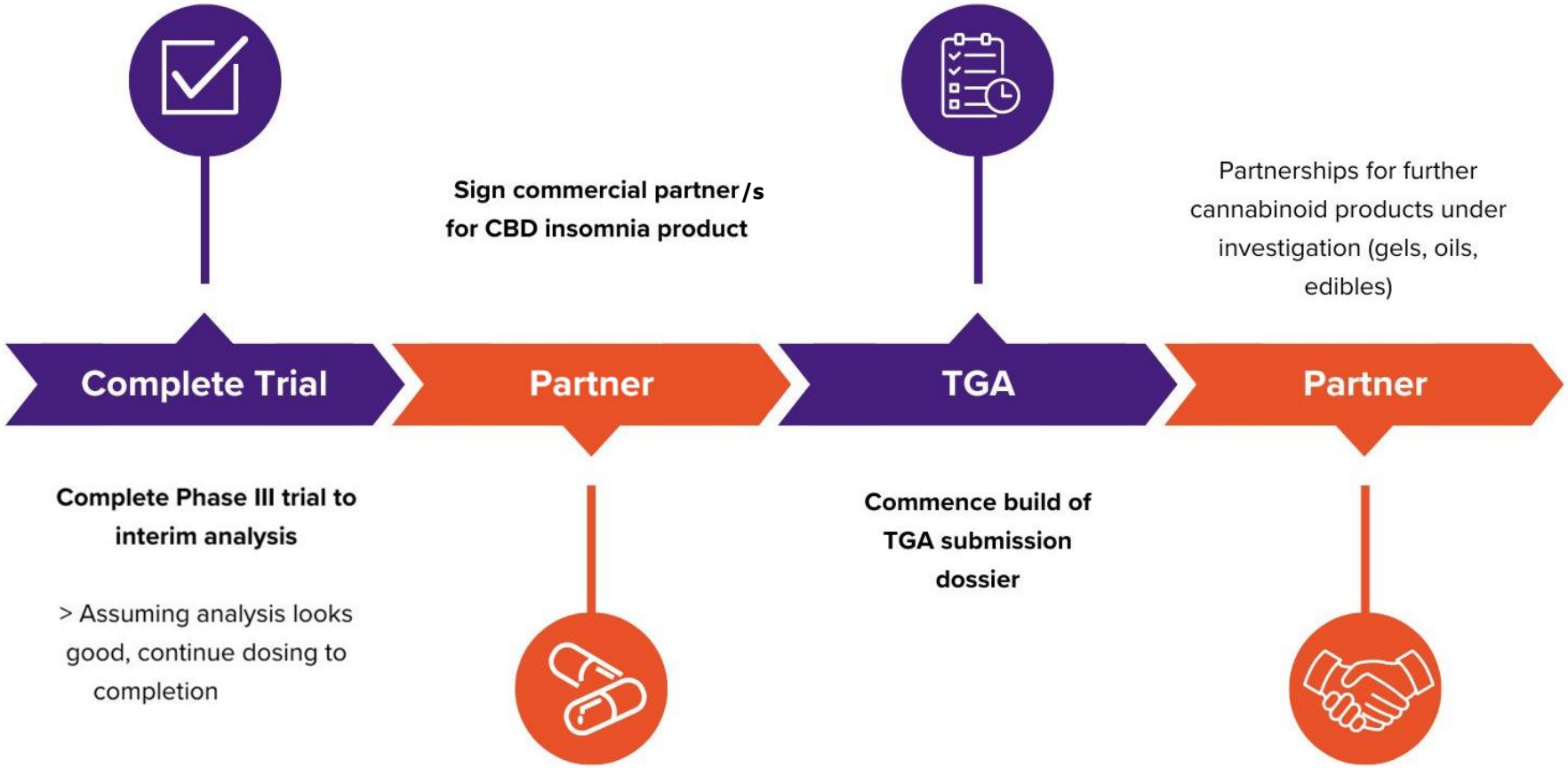
- Avecho's insomnia Phase III is significantly larger and more rigorous, maximizing the chance of a successful outcome.
- Recent results have validated Avecho's trial design decisions and de-risked the study
- Avecho placed to have one of the first CBD products approved by the TGA
- Without competitive products in the space, interested licensees will all need to deal with Avecho

THE OPPORTUNITY

- De-risked Phase 3 trial heading toward interim analysis – key inflection point
- Potential to be the first over-the-counter CBD sleep capsule – first mover advantage
- Outstanding partnering potential – significant interest from major pharmaceutical companies
- Avecho's TPM technology significantly increases absorption, efficacy & thus chance of success – key points of difference
- Addressing a major unmet need that costs the economy billions:
  - Over 3M Australians experience insomnia which costs the Australian economy $19.1 billion per annum[1]
  - Sleep economy & sleep aids market estimated to reach US$950.22 billion by 2032[2]
- Forecast to be one of the biggest pharmaceutical products in Australian history

[1] https://www.deloitte.com/au/en/services/economics/analysis/rise-try-to-shine.html
[2] https://finance.yahoo.com/news/sleep-economy-sleep-aids-market-133100851.html

THE YEAR IN FRONT OF US



QUESTIONS WELCOME

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