OCTOBER 2023

Avecho

PHASE III SHAREHOLDER WEBINAR

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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.

AGENDA

1. Capital Raise
2. Phase III trial design & timeline
3. Recent third-party results; implications for Avecho's trial

CAPITAL RAISE

Entitlement Offer – $2M

- 323M New Shares issued to existing shareholders, raising **approximately $2M** (May)
  - Allowed **Phase III manufacturing** activities to commence

Shortfall Placement – $6M

- Tranche 1 – 536M New Shares raising **$3.2M** (September)
- Tranche 2 – 471M New Shares raising **$2.8M** (November)
  - EGM (9 November) for shareholder approval of Tranche 2

AVE Corporate Summary[1]	
Total shares (including T2)	3.17 Bn
Total options (including T2)[2]	2.37 Bn
Cash (end Q2 2023)	A$2.86 M
+ T1	A$3.20 M
+ T2	A$2.80 M
Total cash	A$8.86 M
MCAP[3]	A$12.14M

[1] Assuming shareholder approval of all EGM resolutions
[2] Various exercise price and expiry dates
[3] As of 12th October 2023

PHARMACEUTICAL CANNABIDIOL IS VALUABLE

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]
- **It is anticipated that registered pharmaceutical CBD products for broader indications would be more valuable**

Avecho is targeting large indications such as insomnia for its pharmaceutical CBD product – large commercial opportunity

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

INSOMNIA IN AUSTRALIA – UNIQUE CBD OPPORTUNITY

Insomnia can be broadly defined as difficulty initiating or maintaining sleep

The TGA allows 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]

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[3]

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

- **40%** of Australians getting less sleep than they need
- **59.4%** Experience symptoms 3-4 times per week
- Only **20%** report their sleep is uninterrupted
- Costs Australian economy $19.1 B per annum
- Australian insomnia market **~$250M per annum**
- Global insomnia market **>$4B per annum**

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

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)
3. 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.

SCIENTIFIC ADVISORS

Assoc Professor Darren Mansfield

Deputy Director, Monash Health

- Director Sleep Service, Monash Health
- Expertise across full range of sleep disorders, including insomnia
- Significant experience in the conduct of large insomnia trials
- Principal investigator for the Avecho study

Professor Shantha Rajaratnam

Deputy Director, Turner Institute for Brain and Mental Health

- Academic Head of School of Psychological Sciences
- Expert in the sleep-wake cycle and the study of novel treatments for sleep disorders in clinical trials.
- Chair, Sleep Health Foundation; past-President Australasian Sleep Association

Assoc Professor Michael Perlis

Assoc Prof Psychiatry, Behavioral Sleep Medicine Program, (Penn Uni)

- Expert in insomnia and behavioral sleep medicine (BSM) clinical trials.
- Editorial boards of Sleep, Sleep Research, Sleep Medicine Research and Behavioral Sleep Medicine
- Past committee member; Sleep Research Society, American Academy of Sleep Medicine, Society of Behavioral Sleep Medicine

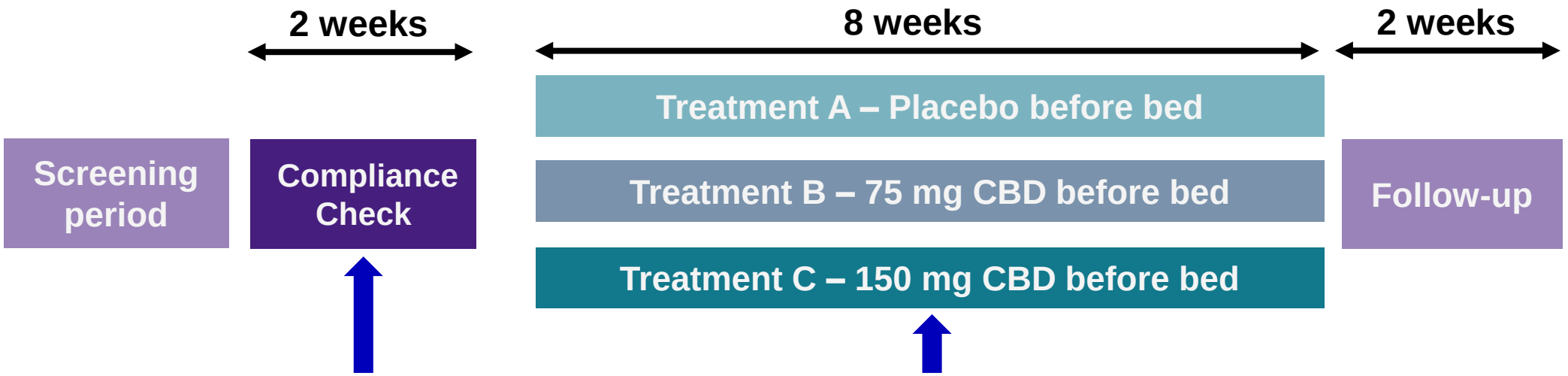
Prof Sean Drummond

Professor of Clinical Neuroscience (Monash Uni)

- Director of Sleep and Circadian Research (Turner Institute for Brain and Mental Health)
- Specialist in the cognitive neuroscience of sleep, the treatment of insomnia and wearable devices used to measure sleep in clinical trials.
- Research funded by NIH, NHMRC, US Department of Defense and industry

PHASE III STUDY DESIGN

Based upon study design from recently approved insomnia medications (Dayvigo, Quviviq)



Five Clinical Trial Sites in 4 States

- Victoria (Melbourne)
- NSW (Western Sydney and Central Coast)
- Queensland (Brisbane)
- Western Australia (Perth)

Patient Numbers

Total n=519

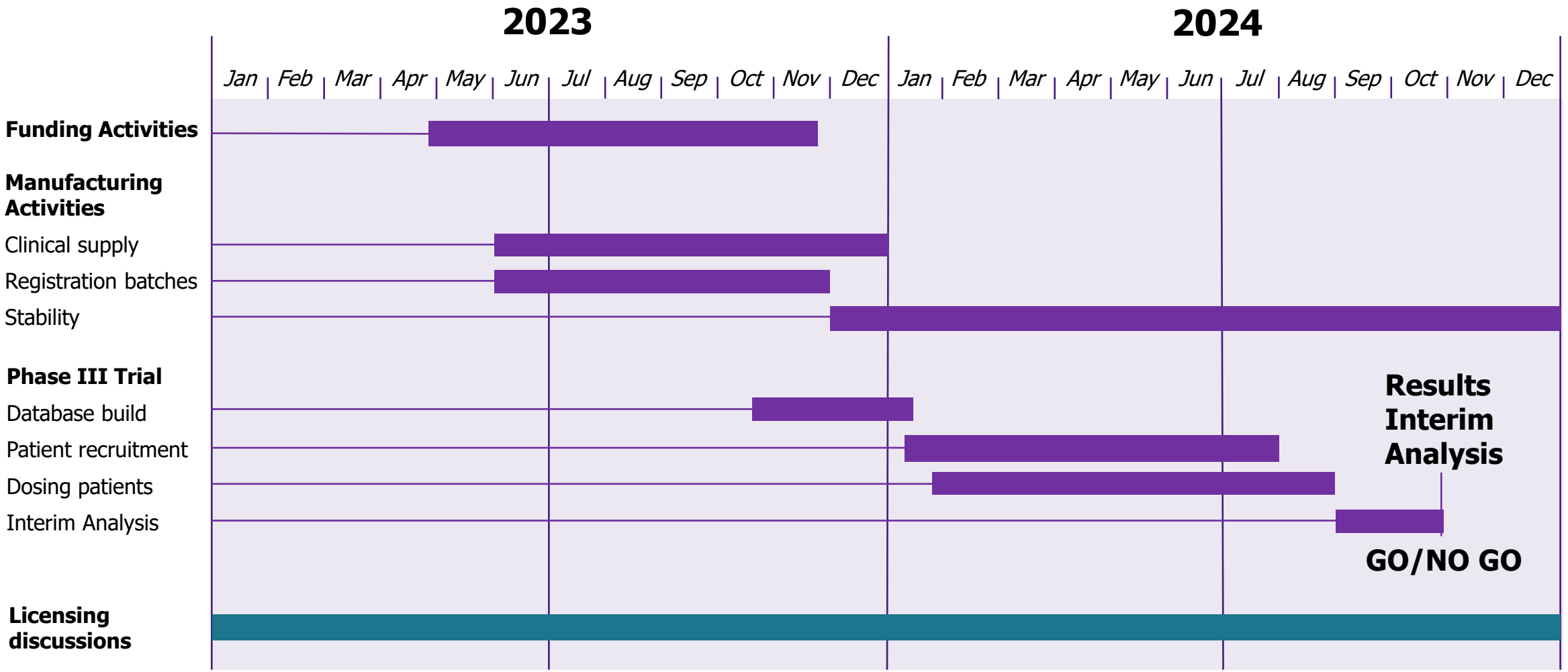
N=173 per group

Interim Statistical Analysis

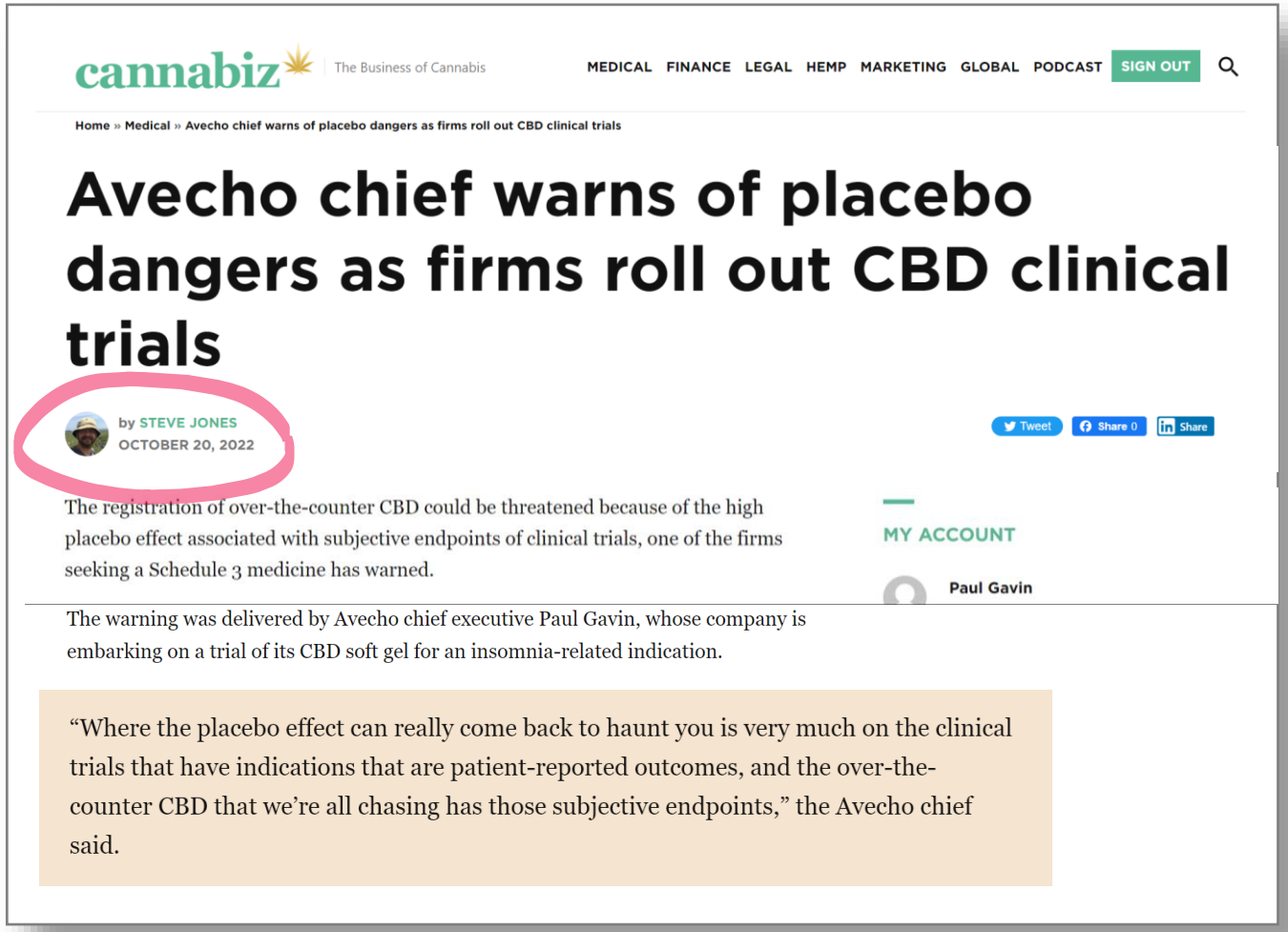
Conducted after ~210 patients

Used to confirm an effect between groups (futility) and calculate additional patient numbers required for success

TIMELINES TO INTERIM ANALYSIS - MAJOR GO/NO GO



THE DANGER OF THE PLACEBO RESPONSE



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MEDICAL FINANCE LEGAL HEMP MARKETING GLOBAL PODCAST SIGN OUT

Home » Medical » Avecho chief warns of placebo dangers as firms roll out CBD clinical trials

Avecho chief warns of placebo dangers as firms roll out CBD clinical trials

by STEVE JONES
OCTOBER 20, 2022

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The registration of over-the-counter CBD could be threatened because of the high placebo effect associated with subjective endpoints of clinical trials, one of the firms seeking a Schedule 3 medicine has warned.

MY ACCOUNT

Paul Gavin

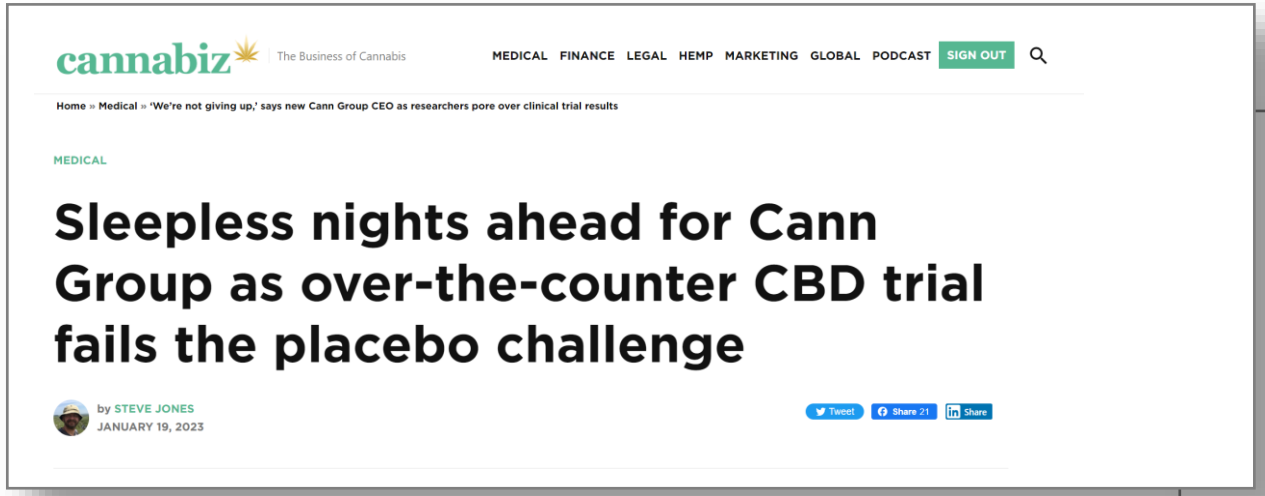
The warning was delivered by Avecho chief executive Paul Gavin, whose company is embarking on a trial of its CBD soft gel for an insomnia-related indication.

"Where the placebo effect can really come back to haunt you is very much on the clinical trials that have indications that are patient-reported outcomes, and the over-the-counter CBD that we're all chasing has those subjective endpoints," the Avecho chief said.

- A placebo effect is when a patient reports improvement in their condition after taking a pretend (placebo) medicine
- Trials with subjective endpoints (like insomnia) have high placebo effects
- The placebo effect makes it difficult to monitor a drug's effect, minimizing the chance of success in clinical trials
- Avecho went on record (left)[1] in 2022, describing the risks to the industry for upcoming CBD trials
- In Q1 CY23, two Phase III trials examining CBD for insomnia announced their failure

Sources:
1. https://www.cannabiz.com.au/avecho-chief-warns-of-placebo-dangers-as-firms-roll-out-cbd-clinical-trials/

FIRST CLINICAL TRIAL RESULTS



However, Koetsier revealed it wasn't that Satipharm hadn't worked, but that the improvements were not discernibly different to participants on the placebo.

"It's not as if participants failed to see any benefits, and that it flatlined, [it was] quite the opposite," he told *Cannabiz*. "But everyone did better in the study, including the placebo group. So it doesn't mean that Satipharm doesn't work. It means we weren't able to prove it using this particular protocol on those particular patients."

"Ecofibre's phase 3 clinical trial... was officially completed in the quarter and initial results show that whilst there was improvement in sleep outcomes compared to baseline, the improvements did not reach statistical significance compared to placebo," the company said.

Sources:
1. https://www.cannabiz.com.au/blow-for-cann-group-as-over-the-counter-cbd-trial-fails-to-show-efficacy-for-sleep-disturbance/
2. https://www.cannabiz.com.au/were-not-giving-up-says-new-cann-group-ceo-as-researchers-pore-over-clinical-trial-results/
3. https://cdn-api.markitdigital.com/apiman-gateway/ASX/asx-research/1.0/file/2924-02622367-3A611160?access_token=83ff96335c2d45a094df02a206a39ff4
4. https://www.cannabiz.com.au/ecofibre-becomes-second-firm-to-confirm-disappointing-sleep-trial-results/
5. https://cdn-api.markitdigital.com/apiman-gateway/ASX/asx-research/1.0/file/2924-02624508-2A1427262?access_token=83ff96335c2d45a094df02a206a39ff4

MOST RECENT TRIAL RESULTS – BOD

On 6 September 2023 BOD Science Limited (ASX:BOD) announced results of its study assessing CBD for insomnia. BOD tested two doses of CBD (50mg & 100mg) versus placebo in 208 patients over 8 weeks[1]

Primary endpoint failed, showing no improvement in insomnia ($p<0.025$) vs placebo with CBD in the intent to treat population[1]

Post-hoc analysis (per protocol population) showed improved sleep ($p<0.05$) for 100mg CBD versus placebo, but not 50mg CBD[1]

KEY TAKEAWAYS

- CBD works for sleep at higher doses
- Higher patient numbers are required to achieve statistical significance in the ITT population
- Avecho's study overcomes both these limitations
- ***BOD's trial result has de-risked Avecho's study***

Trial Parameters	BOD [2]	Avecho
CBD Dose	50mg CBD and 100mg CBD	75mg CBD and 150mg CBD (with increased absorption)
Patient Numbers	208	519
Insomnia measurement	Insomnia Severity Index (ISI)	ISI and sleep efficiency (SE)
Minimum Inclusion criteria (ISI)	ISI score of 8	ISI score of 15
Controls to minimise placebo effect	No	Yes
Interim analysis for repowering	No	Yes

Sources:
1. https://bod.irmau.com/site/pdf/a8f90a8e-1ab4-401c-bf51-16894af17582/Schedule-3-CBD-trial-preliminary-results.pdf
2. https://clinicaltrials.gov/study/NCT05253417?spons=Bod%20Australia&aggFilters=funderType:industry&rank=1

THE OPPORTUNITY OPEN FOR AVECHO

- After four Australian companies pursued Phase IIb/III clinicals in insomnia targeting TGA registration, three have completed trials and failed to meet their primary endpoint

This leaves **Avecho as the last company** of the initial group in active clinical development

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

Questions welcome via our InvestorHub platform.

Register interest in participating in our Phase III insomnia study at the following link;

cbdinsomniastudy.com