ASX Announcement

23 May 2023

Chair's Address & CEO Presentation

Melbourne, **Australia, 23 May 2023** - Avecho Biotechnology Limited (ASX: AVE, "Avecho", or "the Company") attaches the Chair's Address and the Chief Executive Officer's Presentation for the Annual General Meeting of 23 May 2023 to be held on Level 22, Collins Square, Tower 5, 727 Collins Street, Melbourne VIC 3008 at 1.00pm (AEST).

For enquiries, please contact
Ms Melanie Leydin
Company Secretary
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This announcement has been authorised by the Board of Directors of Avecho Biotechnology Limited.

About Avecho
Avecho Biotechnology Limited (ASX: AVE) develops and commercialises innovative Human and Animal Health products using its proprietary drug delivery system called TPM® (Tocopherol Phosphate Mixture). 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 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.

See more here - avecho.com.au

Forward-Looking Statements
Certain statements in the Chair's Address and the Chief Executive Officer's Presentation 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.

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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.

Chair's Address

Dear Shareholders,

I am pleased to share a Company update on behalf of Avecho Biotechnology Limited to coincide with our Annual General Meeting ("AGM") today.

This year has been important for the Company. We have completed all the necessary steps and built on our expertise in the clinical trial space to be ready for the Company to commence a Phase III clinical trial. To be in this position and be able to initiate a pivotal trial with our own proprietary treatment is the aim of all biotechnology companies.

We are now ready to deliver a Phase III clinical program for our proprietary CBD soft-gel capsule for the treatment of insomnia. The trial has been carefully designed to deliver results that will form the basis of discussions with key regulators and commercial developers. The cannabis market is already significant in Australia and worth over USD60M and expected to grow to over USD500M in 2030[1].

This trial is a transformative milestone for our Company. The research and development to arrive at this opportunity has been completed carefully with rigour, meticulous planning, and adherence to solid scientific practice.

We are grateful for your patience and continued support and following the completion of the necessary capital raise we will be able to execute this strategy for all shareholders.

Key Achievements include:

> Phase III Clinical Program: CBD Soft-Gel Capsule

Since turning our attention to CBD three years ago, Avecho has now successfully navigated all necessary checkpoints ahead of the largest hurdle in pharmaceutical development – the successful completion of a pivotal Phase III clinical trial.

Our Phase III study will be a rigorous investigation of the effectiveness of our proprietary CBD soft-gel capsule for the treatment of insomnia. The TGA has never assessed CBD in a submission package for pharmaceutical approval – similarly, no regulatory agency in the world has approved CBD for an insomnia indication.

We have engaged with leading clinical sleep researchers in Australia and internationally to design and conduct this study. It is one of the largest of its kind in the world, with plans to recruit 500+ participants. It needs to be this large, as we have already seen this year that smaller, less rigorous studies, have not been successful. We do not enjoy the failures of our peers in this space, but we have learnt from some of the errors, justifying our decision to build a study as large as ours.

We remain confident that the resulting data will support registration with the FDA, EMEA and TGA – a defining clinical and commercial achievement for our Company.

> Expanding Cannabinoid Portfolio

There is mounting clinical evidence to support the powerful versatility of our proprietary CBD-TPM® combination. Together with key commercial and research partners, Avecho is on track to deliver up to seven other clinical trials in 2023, which includes internationally recognised work underway with the Lambert Initiative.

We are continuing to explore the effectiveness of a topical CBD TPM® formulation in the treatment of osteoarthritis of the hand, in partnership with the Lambert. The outcomes from our Phase IIa study, which demonstrated significant improvements in self-reported measures of pain, grip strength, finger stiffness and hand functionality, now warrant further investigation in a larger placebo-controlled study.

Having demonstrated the increased absorption of CBD from both our oral and topical dosage forms, we have now manufactured these same dosage forms incorporating THC, CBG, CBC and CBN, to extend the portfolio of cannabinoid products available with increased absorption.

[1] Australia Legal Cannabis Market Size, Share & Trends Analysis Report by Source (Marijuana, Hemp), by Derivative (CBD, THC), by End-use (Medical Use, Recreational Use, Industrial Use), and Segment Forecasts, 2022-2030 (researchandmarkets.com)
Legal Cannabis Market Size, Share & Trends Report, 2030 (grandviewresearch.com)

The topical CBG TPM® formulation has already been earmarked for a subsequent Phase II clinical trial with the Lambert Initiative, with the trial documentation currently under development.

Most recently, the Company has begun to develop THC gummies with TPM. These early prototypes are already generating commercial interest. But we will wait to reveal more of these in the future. While we focus on their medicinal applications, it is obvious what these types of products could mean for the North American recreational cannabis industry.

> Business Development: Sealing deals with TPM®

In the last 12 months, Avecho announced three new partnerships with international pharmaceutical companies, Perrigo, Athenex, and Arthur Group to support the continued development of pharmaceutical products enhanced with TPM®.

Perrigo was drawn to compelling evidence that TPM® may improve the performance of ibuprofen gels – a market opportunity which is yet to be exploited in the US. Perrigo is planning to conduct a clinical trial in a pain-related indication using the ibuprofen TPM® gel this year.

Global biopharmaceutical company, Athenex, also submitted Avecho's TPM®-enhanced phytonadione injectable product to the FDA for feedback via a pre-IND meeting request. If the FDA feedback is positive, we intend to finalise a license and development agreement with Athenex and support its US registration.

Further to this, just yesterday we announced an agreement with the Arthur Group for the develop of TPM®-powered oncology drugs. Oncology drugs often are difficult to dissolve, require solvents or surfactants with a range of unwanted side effects. The Arthur Group will look to replace these ingredients with TPM®, replacing adverse ingredients with our friendlier form of Vitamin E. If successful, these TPM® oncology formulations could readily displace some of the huge blockbusters that dominate the market.

Capital Raise

Finally, I wanted to touch upon the capital raise the Company has recently embarked on. The Company is seeking a large amount of money in a time of financial hardship, when the market cap is at a two-year low. The Board did discuss the implications of this raise, and what it would or could mean for existing shareholders. But ultimately, the Board determined that the value to shareholders of this Phase III trial far outweighed any short-term pain.

We acknowledge that many of you were unable to contribute and suffered dilution as a result. But we firmly believe that the growth in value from a successful Phase III clinical trial will provide a great upside for the Company and more than compensate all shareholders.

While our capital raise to fund the study is ongoing, our shareholders contribution has already allowed us to commence the initial Phase III activities with the manufacture of our product. We thank you all for your continued trust in the program we are undertaking.

Conclusion

On behalf of the Avecho team I would like to express our sincere gratitude for your support this year. Particularly those that have backed our capital raise and those supporting our considered efforts to build our profile as a differentiated leader in the CBD space.

Thank you,

Dr Gregory Collier
Chairman of Avecho Biotechnology Limited

ANNUAL GENERAL MEETING

23RD MAY 2023

Avecho

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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 commercialisation 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. Develop, TGA register and commercialise a proprietary pharmaceutical CBD capsule containing TPM

2. License this and other TPM cannabinoid dosage forms in multiple indications, territories and markets

THE GLOBAL CANNABIS MARKET IS ALREADY HUGE

Global Legal Cannabis Market

- Legal use (medicinal or adult) in 30 countries
- Valued at $17.8 billion USD in 2021
- 65.0% of the market in North America in 2021
- Projected compound annual growth rate (CAGR) of 25.3%
- Expected to reach $73.6 billion USD by 2027

Australian Cannabis Market

- Medicinal use only
- $66 million USD in 2022
- Expected to reach $540.6 million USD by 2030
- Projected CAGR of 30.1%

Despite the global value of the cannabis market, the products have become commodities with little commercial differentiation

AVECHO'S TPM® PROVIDES COMMERCIAL DIFFERENTIATION

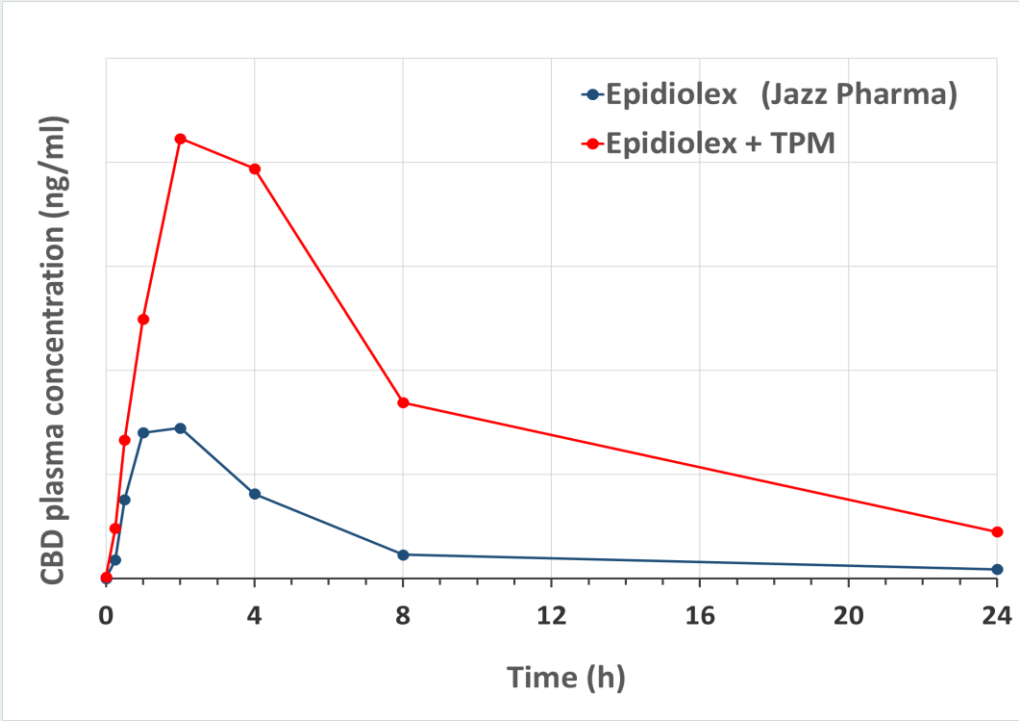
Cannabinoids such as cannabidiol (CBD) are lipid soluble molecules with poor oral absorption (~6%)

TPM increases absorption of lipids, including cannabinoids

Increasing cannabinoid absorption produces;

- ✓ Greater therapeutic effect
- ✓ New indications, previously untreatable because of high doses required
- ✓ Reduced dosing for cost savings to patients
- ✓ Provides **commercial differentiation**

Increased oral CBD absorption



PHARMACEUTICAL CANNABIDIOL IS VALUABLE

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

- Epidiolex was developed by GW Pharma
- Approved for rare childhood epilepsy conditions – rarely prescribed
- GW Pharma was acquired for **$7.2Bn USD** by Jazz Pharma (2021) to obtain Epidiolex

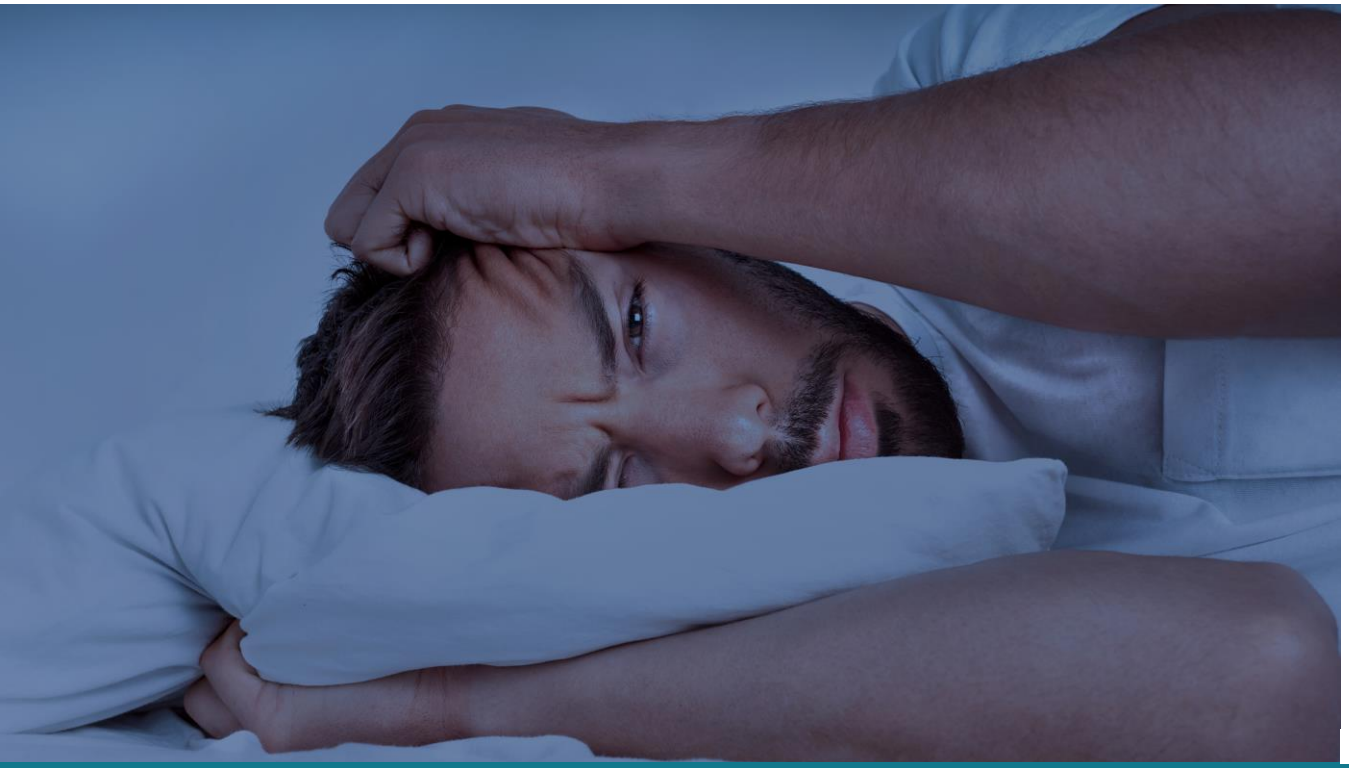
- **It is anticipated that registered pharmaceutical CBD products for broader indications would generate larger markets**

Avecho is targeting large indications like insomnia for its pharmaceutical CBD product, a huge commercial opportunity

CBD FOR THE TREATMENT OF INSOMNIA

Insomnia is defined as difficulty initiating or maintaining sleep

Growing body of prescribing information suggesting that CBD may alleviate the symptoms of insomnia.



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

~$250M p.a. spent on existing medications with unwanted side effects

Costs Australian economy $19.1 B per annum

Global insomnia market **>$4 B per annum**

UNIQUE AUSTRALIAN OPPORTUNITY

- The Australian Therapeutic Goods Association (TGA) has allowed pharmaceutical CBD products to be registered as over-the-counter (OTC) medicines.
- OTC medicines are available direct from a pharmacist without a prescription, a significant commercial advantage over the existing medicinal cannabis products that require a prescription

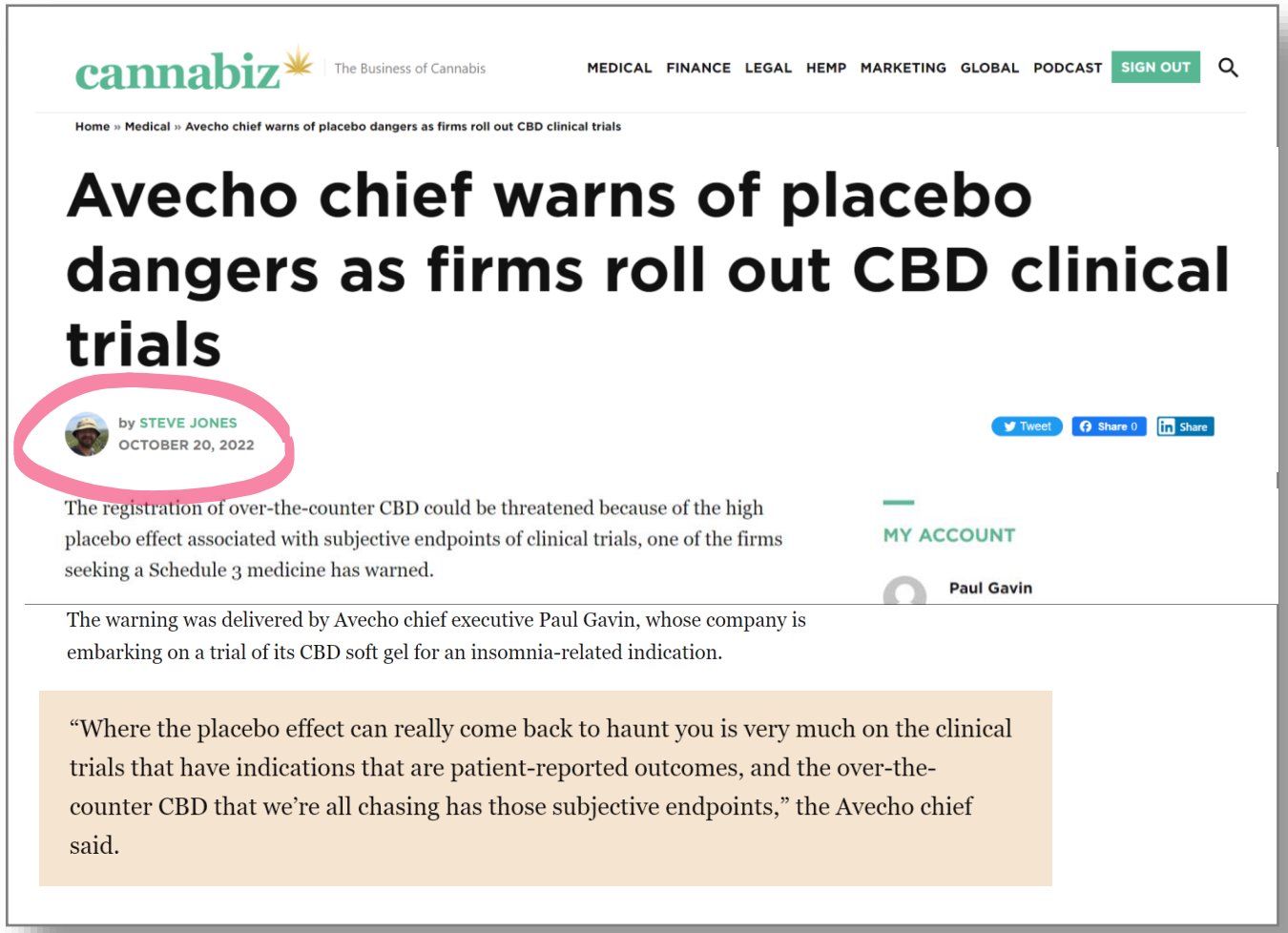
OTC registration will be difficult, but the difficulties play to Avecho's strengths

OTC Requirement	Challenge	Avecho Advantage
Maximum dose of 150mg CBD per day	150mg of CBD is considered a low dose and may not prove effective	A product with increased absorption acts like a higher dose
Clinical trials proving CBD is effective	CBD has not been proven to work for insomnia in Phase III clinical trials, making trial design hard	Avecho has significant experience in the design and conduct of clinical trials using a range of drugs
Pharmaceutical manufacturing with 2 year shelf life	CBD can degrade over time in formulations, making it difficult to demonstrate a 2 year shelf life	Avecho's CBD product was developed for pharma stability, with first batches already passing 1.5 years stability

This CBD opportunity is currently unique in the world

Avecho is ideally positioned to be one of the first to successfully register a CBD product for the OTC market

CLINICAL TRIAL DESIGN EXPERTISE IS CRITICAL



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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) in 2022, describing the risks to the industry for upcoming CBD trials
- In 2023, the first two Phase III trials investigating CBD for insomnia announced their failure, attributing this result to the placebo effect

PHASE III STUDY DESIGN

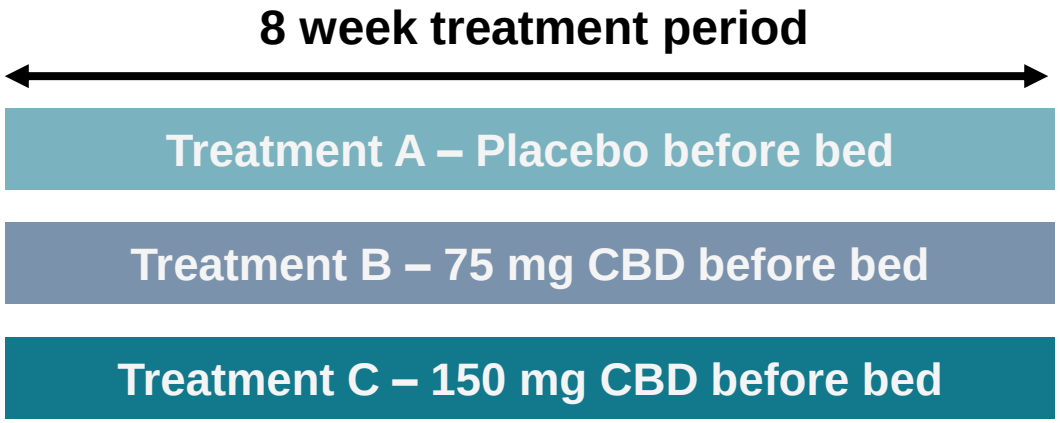
Based upon study design from FDA approved insomnia medications

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 (540 patients)**
- **Higher insomnia scores required for inclusion**
- **Longer dosing period (8 weeks)**
- **An interim analysis (after 300 patients) to calculate required patient numbers**
- **Methods to minimise the placebo effect**

Assessments include;

- Daily sleep diary to record nightly sleep.
- Sleep questionnaire every two weeks.
- Wearable device to record daily objective sleep data
- Secondary endpoints related to anxiety



PHASE III TRIAL COSTS – CAPITAL RAISE

Chemistry, Manufacturing and Control (CMC) – (~$1.3M AUD)

Pivotal Phase III clinical trial – (~$11M AUD)

TOTAL

- $~**12.3M AUD**

Cap Raise for ~$11M AUD*

Two parts;

- **Entitlement Offer to Shareholders**
- **Placement of shortfall to new investors**

*R&D tax credits reimburse 43.5% of this spend

CAPITAL RAISE PROGRESS

Entitlement offer – Existing Shareholders

- ~323M New Shares and ~486M New Options issued, raising **approximately $2M**
- Interest for a further ~$1M in shortfall from existing sophisticated and institutional shareholders
- **~$2M received is enough to commence Phase III trial activities**

Shortfall – New Investors (with support expected from sharedholders)

- Avecho to place approximately $8M with new investors
- Joint-Lead Managers running the process (CPS Capital and Peak Asset Management)
- Looking to place shortfall in the coming month/s

REMAINING DEVELOPMENT PROGRAM (2023-24)

Chemistry, Manufacturing and Control (CMC)

- Further CMOs engaged for access to other markets (**complete**)
- Manufacturing scale up to registration batch (1/10th commercial scale) size (**ongoing**)
- Registration batches to be submitted for formal stability (**Q3 2023**) – Paid for by entitlement offer
- Complete CMC dossier for use in registration dossier (**2024**)

Phase III sleep indication

- Study design finalised (**complete**)
- Service providers actively identified and engaged (**complete**)
- Ethics approval (**complete**)
- Clinical supply available for dosing (**Q3 2023**) – Paid for by entitlement offer
- Interim analysis (**Q1 2024**)

Regulatory Submission – Compile and submit dossier to TGA (**2024**)

Commercialisation – Partner to commercialise product in ANZ; Avecho to license product ROW

NEW PARTNERSHIPS

Perrigo to develop AVE's ibuprofen gel for US market

Athenex considering TPM injectables. Have taken Vitamin K TPM to FDA pre-IND

Arthur Group to develop TPM oncology injectables

Lambert to conduct two clinical trials with AVE's CBD capsule. Also partnering on topical CBD/CBG trial

MULTIPLE CLINICAL TRIALS IN 2023

Avecho products will be in multiple clinical trials in 2023, the majority funded by third parties.

- Continuous news across multiple products and multiple indications
- Positive results from any of these studies will lead to compelling commercial opportunities.

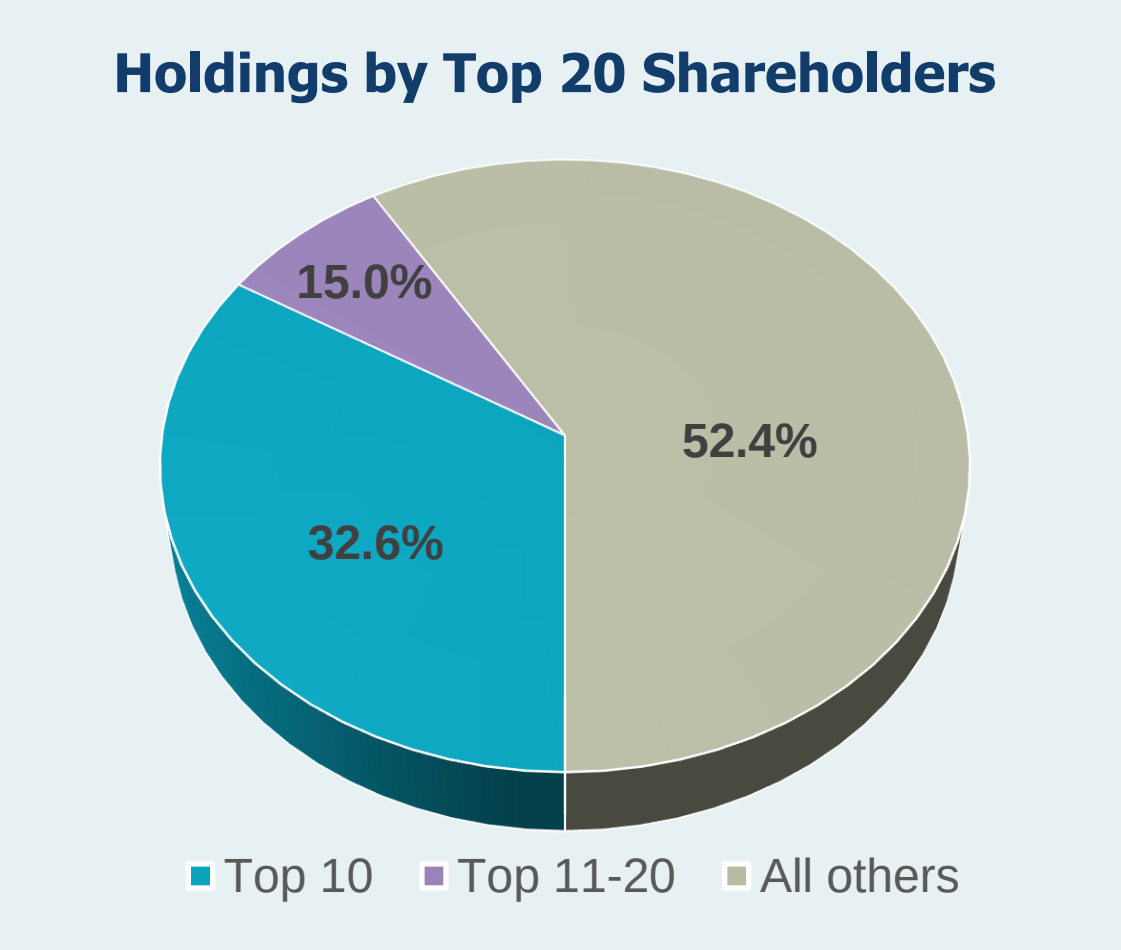
Product	Therapeutic Area	Funded by	Phase
CBD Capsule	**Sleep**	**Avecho**	3
CBD Capsule	Osteoarthritis	Perland	1b
CBD Capsule	Confidential	Lambert Initiative	1b
CBD Capsule	Confidential	Lambert Initiative	1b
CBD Topical Gel	Osteoarthritis	Avecho/Lambert	2
CBG Topical Gel	Osteoarthritis	Avecho/Lambert	2
Ibuprofen Topical Gel	Pain	Perrigo	1b

COMPANY SNAPSHOT (MID RAISE)

Cash	$0.924M[1]
	+ $0.627M (tax refund)
	+ $2M (entitlement offer)

As of 22nd May;

Shares	2,162M
Market cap	~$12.9M
Options	706M



[1] *As of 31 March 2023*

VALUE DRIVERS

- Pivotal **Phase III trial** for an insomnia indication ready to go
    - Ethics approval received, manufacturing activities commenced
- **CBD capsule** targeting over-the-counter **registration in Australia,** followed by ROW
    - Huge potential commercial opportunity
- Proprietary **cannabinoid** portfolio **differentiated with TPM® delivery technology**
- **Further clinical trials** being conducted on CBD capsule, **funded by third parties**
- **Further cannabinoid products** under investigation (gels, oils, edibles)
- **Partnerships for non-cannabinoids** products (Perrigo, Athenex, Arthur Group)

QUESTIONS WELCOME

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