APRIL 2023

Avecho

ENTITLEMENT OFFER TO FUND PIVOTAL PHASE III CLINICAL TRIAL

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FAST FACTS

- Avecho is developing **pharmaceutical cannabinoid** products **using TPM® delivery technology**
- First **75 mg CBD capsule completed** with Catalent, USA (May 2021)
- First **human clinical trial (Phase I PK) completed** (Dec 2021) – characterised absorption
- **Pivotal Phase III clinical trial** ready to begin (ethics approval Dec 2022)
- Targeting over-the-counter **registration in Australia,** followed by rest of world
- **Licenses signed** for CBD capsule and TPM in overseas markets (Dec 21-Feb 22).
- **Partnerships** for non-cannabinoid pharmaceutical products (Perrigo, Athenex; Dec 22, Jan 23)

CLEAR STRATEGIC FOCUS

1. Complete Phase III clinical trial testing proprietary pharmaceutical CBD capsule containing TPM

2. Commercialise this, and other TPM cannabinoid products, in multiple markets

CANNABINOIDS AS MEDICINE

- Medicinal cannabis extracts are being legalized around the world
- Some markets are allowing consumer and recreational uses
- Unregistered medicinal cannabis products are being prescribed for a range of therapeutic indications
- Normal R&D into formulation development has been minimal, and the initial product offerings were simple oil-based formulations
- A range of more acceptable dosage forms are required to fulfil the needs of patients, physicians and consumers

THE PROBLEM WITH CANNABINOIDS

Cannabinoids have very poor oral bioavailability; only ~6% of ingested cannabinoids are absorbed

This presents challenges for developing formulations that can deliver cannabinoids to the body efficiently

Increasing cannabinoid bioavailability has become a focus for many laboratories around the world, as increasing bioavailability can allow;

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

Few medicinal cannabis companies have the expertise to address these issues

AVECHO'S TPM® PROVIDES A SOLUTION

TPM is Avecho's proprietary phosphorylated vitamin E product

TPM encapsulates drug molecules to improve their:

- solubility
- stability
- oral bioavailability
- dermal/transdermal delivery

TPM has an excellent safety profile making it ideal for drug reformulation

Cannabinoids have the perfect chemistry for compatibility with TPM

TPM reformulated drugs have:

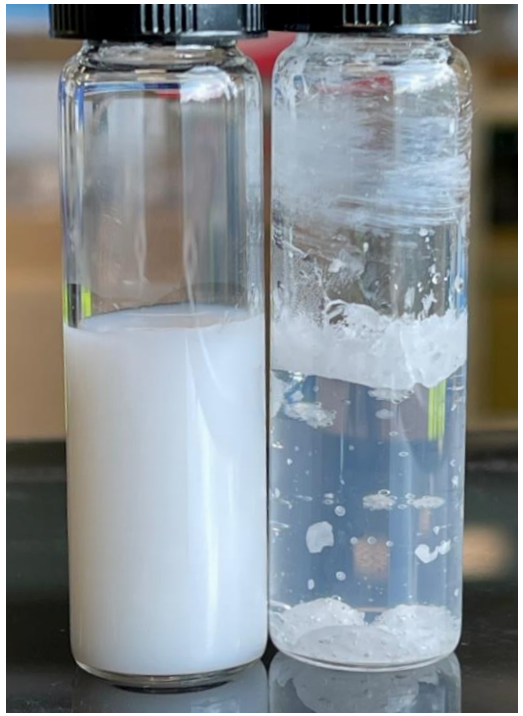
- improved pharmaceutical properties and performance
- Commercial opportunities for differentiation and patent protection

Propofol TPM®

With TPM Without TPM

AVECHO'S TPM SOLUBILIZES CANNABINOIDS

Cannabidiol* Solubility



With TPM Without TPM

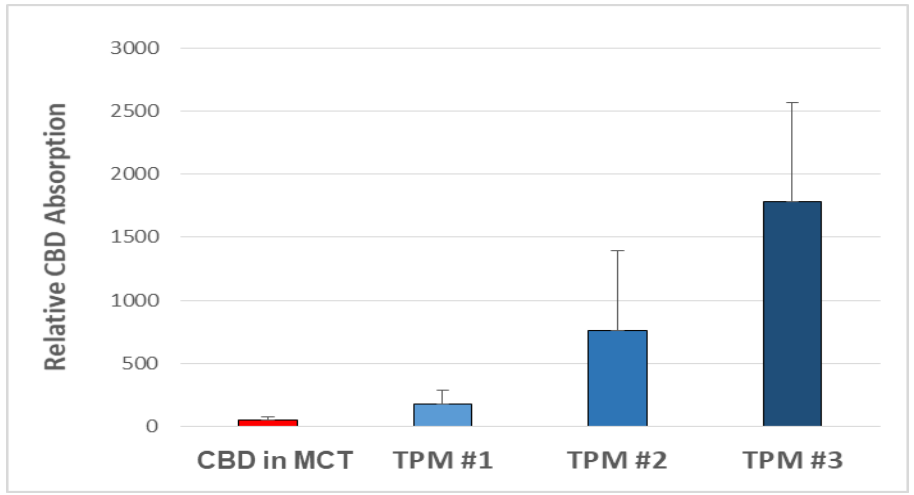
Increased solubility with TPM leads to….

- **Oral** — **Increased oral absorption**
- Topical — **Increased topical absorption**

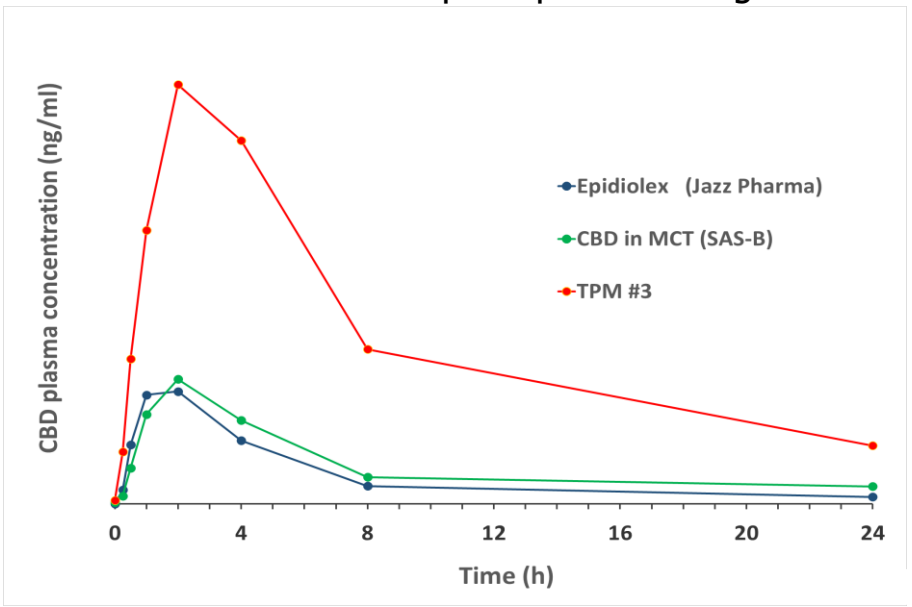
*Cannabidiol (CBD) is the main non-psychoactive cannabinoid in cannabis.

TPM INCREASES ORAL ABSORPTION OF CBD

Total cannabidiol absorbed (AUC) in rats



Cannabidiol absorption profile in dogs



Rodent studies conducted at Bioneer:FARMA in Copenhagen

- ✓ Increases in AUC produced by TPM formulations ranged from ~**4-40 times** in rats

Dog studies conducted at Labcorp in the UK

- ✓ Increases in AUC produced by TPM formulations ranged from ~**3.7-5.6 times** in dogs
- ✓ Better absorption than Epidiolex, the only FDA approved pharmaceutical CDB product

CANNABIS MARKET OVERVIEW

Global Legal Cannabis Market

- Legal use permitted (adult or medical) in 30 countries
- Valued at $17.8 billion USD in 2021
- North America accounted for the largest revenue share, 65.0% 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, currently through unregistered medicine's scheme
- $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 themselves have become commodities with little commercial differentiation

PHARMACEUTICAL CANNABIDIOL IS VALUABLE

There is currently only one pharmaceutical CBD product approved by the FDA (Epidiolex)

- Epidiolex® was developed by GW Pharma
- It is approved by the FDA for rare childhood epilepsy conditions
- 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

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

PHARMACEUTICAL CBD TPM CAPSULE COMPLETE

- Formulations developed by Avecho over the last 3 years; increase CBD absorption in animal models (rodent and dog)
- Capsule design finalised at Catalent, USA (May 21)
- 75 mg of ultra-pure, synthetic CBD (Purisys) per capsule
- Product shows good pharmaceutical stability (ongoing; passed 18 months).
- Phase I pharmacokinetic (PK) study to characterise the CBD absorption completed (Dec 21)
- Phase III clinical trial to be conducted in Australia in a sleep related indication in 2023 (ethics approval Dec 22).
- Product seeking TGA approval as an OTC medicine, followed by rest of world
- International PCT patent applications filed to protect formulation

CBD FOR THE TREATMENT OF INSOMNIA

Insomnia can be broadly defined as difficulty initiating or maintaining sleep.

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

The TGA has confirmed CBD could be registered as an over-the-counter medicine for the treatment of insomnia.

40% of Australians getting less sleep than they need

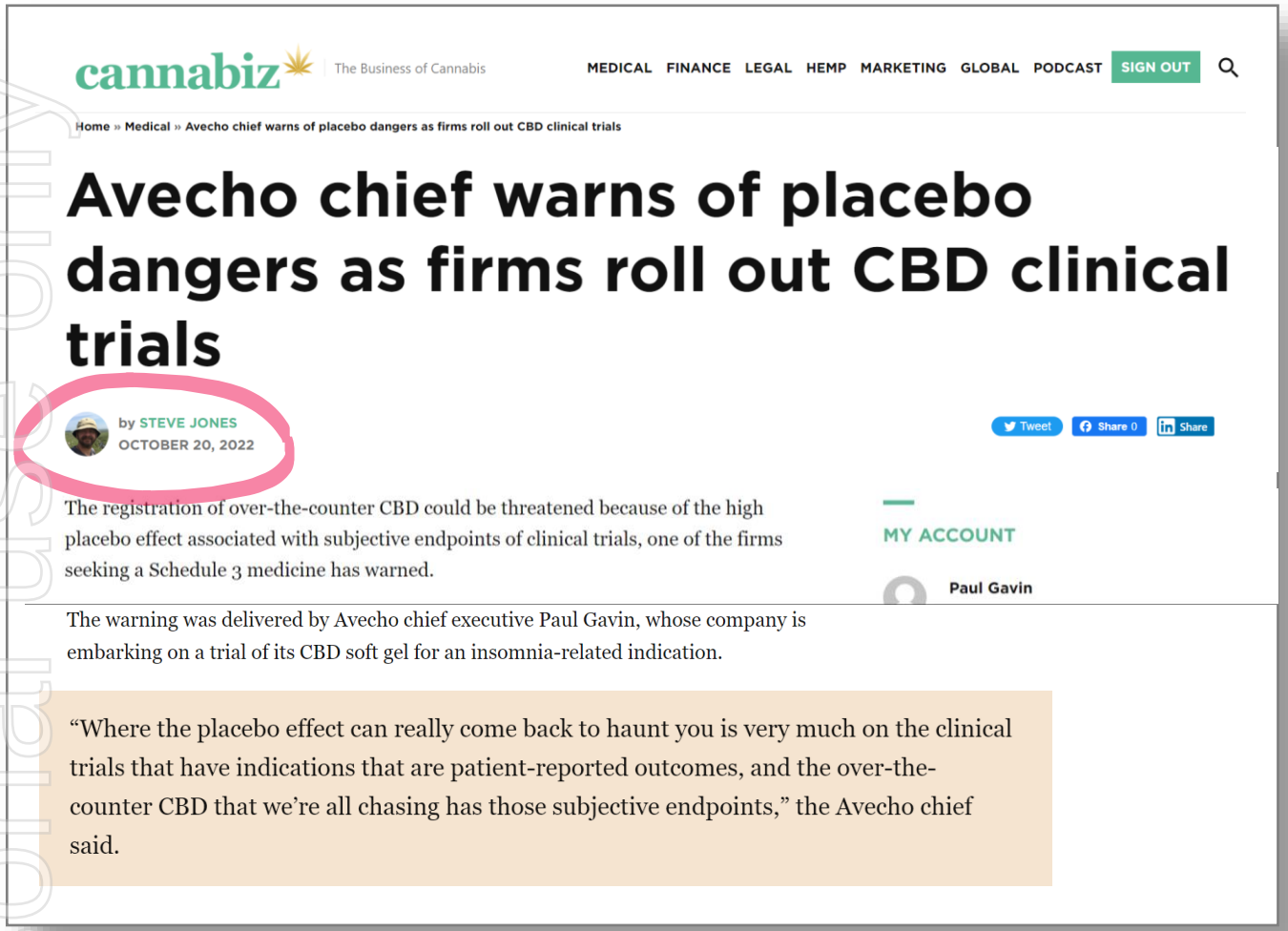
59.4% Experience symptoms 3-4 times per week

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

CLINICAL TRIAL DESIGN EXPERTISE IS CRITICAL



cannabiz The Business of Cannabis

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

Tweet Share 0 Share

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

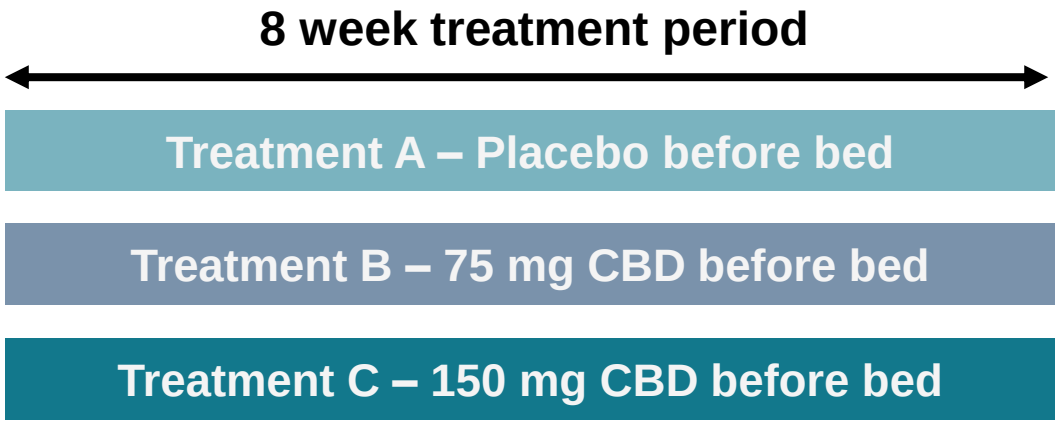
Based upon study design from FDA approved insomnia medications

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



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 (**Q2 2023**)
- Complete CMC dossier for use in registration dossier (**2024**)

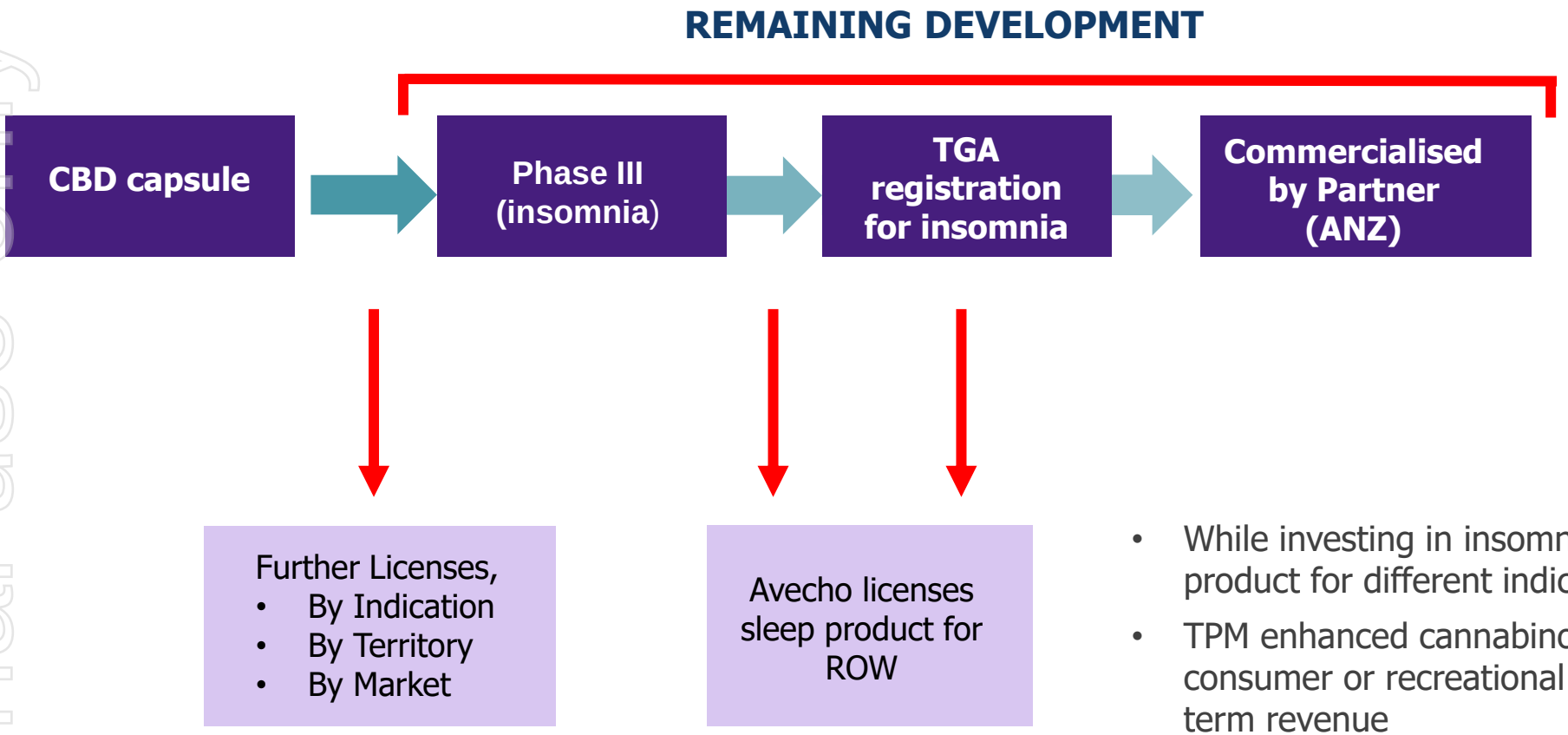
Phase III sleep indication

- Study design finalised (**complete**)
- Service providers actively identified and engaged (**complete**)
- Ethics approval (**complete**)
- Clinical supply available for dosing (**Q2 2023**)
- Interim analysis (**Q4 2023**)

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

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

MAXIMISING VALUE FROM THE CBD PRODUCT DEVELOPMENT



- While investing in insomnia, Avecho can license the CBD product for different indications, territories of markets
- TPM enhanced cannabinoid products can enter the consumer or recreational markets overseas for shorter term revenue

CANNABINOID DEALS ALREADY SIGNED

CBD capsule for arthritis

- CBD capsule licensed (Dec 2021) for arthritis indication (osteo and rheumatoid arthritis), to Perland (Medterra Pharma)
- Medterra are one of the most successful consumer CBD companies in the United States
- Perland will pay for all development; clinical trials to begin 2023

TPM for the US Recreational Cannabis Space

- TPM Licensed (Feb 2022) to Team SAAS for use in a TPM cannabis distillate for the US recreational cannabis market
- Independent research has shown that THC gummies containing TPM work faster and feel stronger than commercially available THC gummies
- Avecho is in further discussions regarding the US recreational cannabis market

More deals to come

FURTHER PRODUCT PORTFOLIO

PORTFOLIO OF DIFFERENTIATED CANNABINOID PRODUCTS

Product	Therapeutic Area	Partner (Geography)	Preclinical	Phase I	Phase II or Observational Study	Phase III	Marketed
CBD Capsule	**Sleep**	**TBD (ANZ)**					
CBD Capsule	Further indications	TBD					
CBD Capsule	Arthritis	**Perland (ROW)**					
CBD Topical Gel	Osteoarthritis	TBD					
CBD Topical Gel	Dermatology	TBD					
THC oil (for use in edibles)	Recreational cannabis	**Team SAAS (USA)**					
THC edibles	Pain, anxiety, etc	TBD					
CBD Oil/Topical Gel	Miscellaneous	Comp pharmacy					

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 Topical Gel	Confidential	Lambert Initiative	1b
CBD Topical Gel	Osteoarthritis	Avecho/Lambert	2
CBG Topical Gel	Osteoarthritis	Avecho/Lambert	2
Ibuprofen Topical Gel	Pain	Perrigo	1b

RECENT PHARMA DEALS

Topical Ibuprofen TPM gel licensed to Perrigo for US market

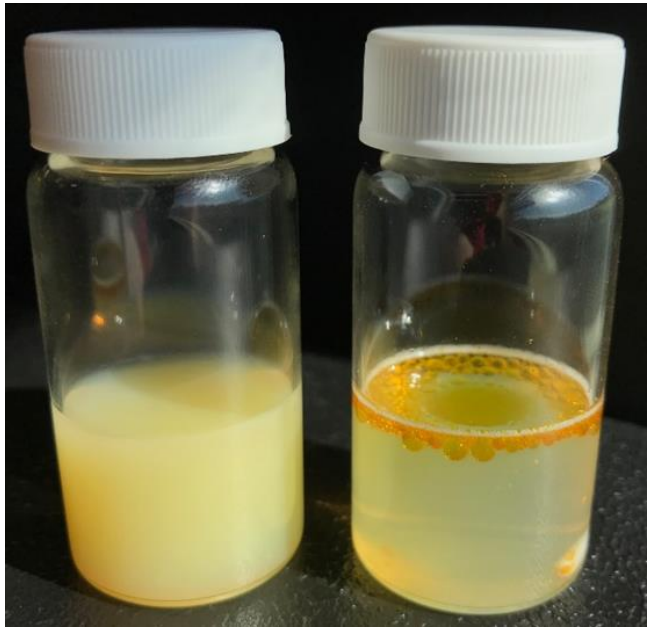
- Perrigo are a leading global consumer company, with brands including Herron, Nicotinell and OsteoEze
- Perrigo to begin clinical development of Avecho's topical ibuprofen gel for the US market in a pain indication
- Would be the first topical ibuprofen product registered in the US

Vitamin K TPM injectable presented to FDA by Athenex

- Athenex is a global pharma company specializing in injectable dosage forms
- Athenex have submitted Avecho's Vitamin K TPM injection to the FDA for comment in a pre-IND
- Favorable FDA feedback will see the execution of a licensing agreement and formal development of the product by Athenex for FDA registration

Heading to FDA

Vitamin K TPM®



With TPM Without TPM

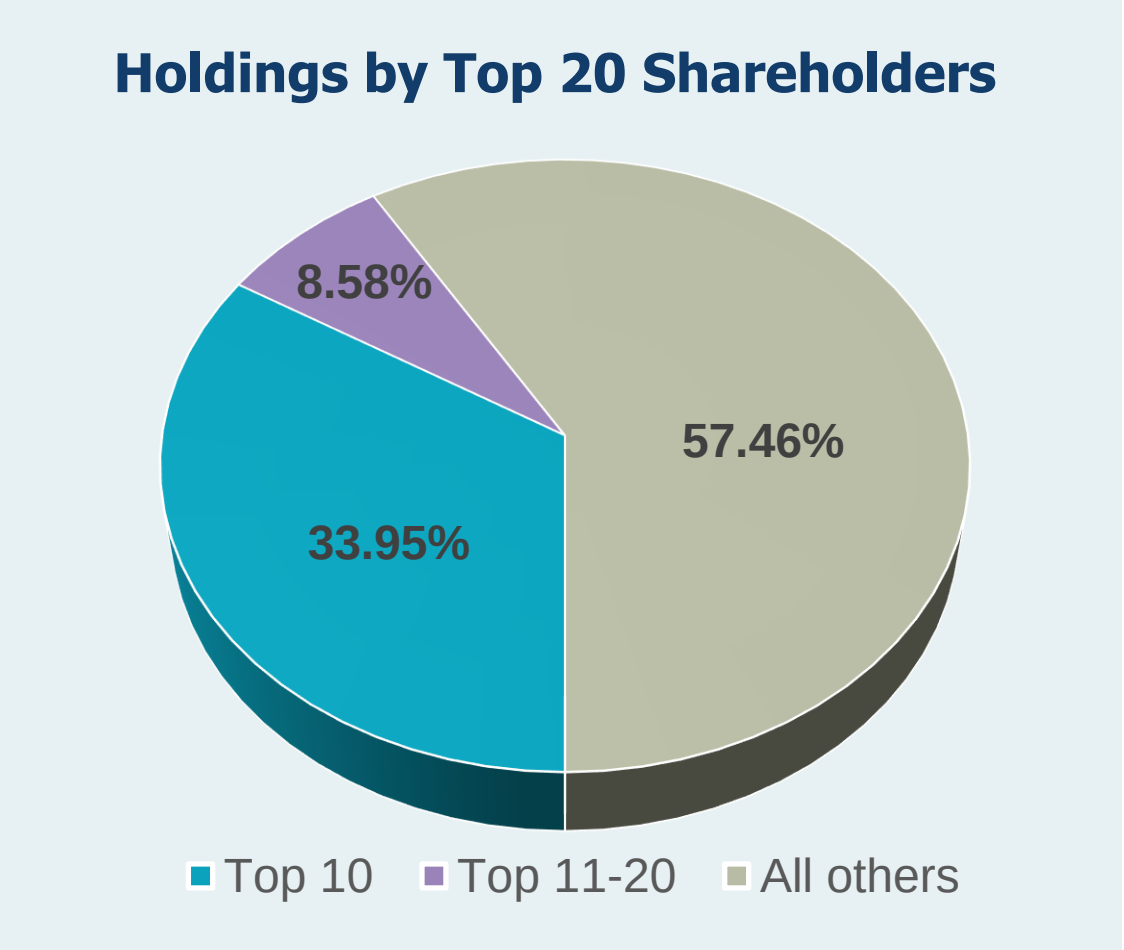
More deals to come

KEY VALUE DRIVERS 2023

- **PHASE III INSOMNIA TRIAL** using oral CBD capsule. Significant re-rate point for the company
- Further **PHASE II OSTEOARTHRITIS** trial using topical CBD gel
- Up to **FIVE ADDITIONAL CLINICAL TRIALS** funded by third parties using TPM products
- Commercial **PARTNERING/LICENSING** opportunities; new markets, new territories, new indications
- New **CANNABINOID PRODUCTS**
- Commercial **PARTNERING/LICENSING** opportunities for traditional, non-cannabinoid pharmaceuticals incorporating TPM (*Perrigo, Athenex, more to come*….)

COMPANY SNAPSHOT

Cash	$1.47M[1]
As of 31st March;	
Shares	1,838M
Market cap	$16.54M
Options	220.3M



[1] *As of 31 December 2022*

AVECHO MANAGEMENT & BOARD

Dr Paul Gavin
Chief Executive Officer

- 20+ yrs Avecho
- Ex- AVE CSO
- Inventor TPM® platform

Dr Roksan Libinaki
Chief Operating Officer

- 20+ yrs Avecho
- Exec MBA
- Co. Operations and clinical

Melanie Leydin
CFO & Company Secretary

- 25+yrs accounting; 15+ yrs Co-Sec
- Inst. of Chartered Accts
- MD Vistra Australia

Dr Greg Collier
Chairman

- 25+yrs biotech exec experience
- ex-CEO Chemgenex (sold $200M+)
- 150 publications, 33 patents

Dr Ross Murdoch
Non-Executive Director

- 25+yrs biotech exec experience
- CEO Extractas
- ex-CEO Avecho (2015-2019)
- ex-SVP Shire Pharma.

Matt McNamara
Non-Executive Director

- 30+yrs experience healthcare
- 20+yr venture capital
- previous CIO Bioscience Managers

THE ENTITLEMENT OFFER

RIGHTS ISSUE OVERVIEW

Avecho is launching a non-renounceable entitlement offer to provide existing shareholders the opportunity to invest in driving next steps across our highly promising Phase III clinical program.

- Under the entitlement offer, all eligible shareholders can subscribe for new AVE shares on a 1:1 pro-rata basis.
- Avecho aims to raise $11,027,216 to progress its pivotal Phase III clinical trial
- Offer priced attractively at 0.6c, a 26.83% discount to the 15-day VWAP as of 31st March
- Each share will include a 3:2 listed option with an exercise price of 1.2c and an expiry of 3 years
- Eligible shareholders will have the opportunity to bid for further shares
- At the conclusion of the entitlement offer the company will place any shortfall

USE OF FUNDS

The Entitlement Offer will raise up to approximately $11 million AUD.

Manufacturing – $1.3M AUD

- GMP manufacture of CBD soft-gel capsule for use in Phase III clinical trials and registration batches for formal stability

Phase III clinical trial - $9.35M AUD

- Main study costs including patient recruitment, investigator and site costs in addition to CRO management of the study

Costs of the Entitlement Offer - $0.35M AUD

It is expected that the total cost of the Phase III clinical trial will be approximately $12 million. The company intends to leverage the research & development tax re-imbursement on the trial spend to fund the day-to-day operations of the company in addition to any cost over-run on the Phase III trial.

RISKS

This section discloses some of the key risks attaching to an investment in Avecho. Before investing or increasing your investment in Avecho, you should consider whether this investment is suitable for you having regard to publicly available information and your personal circumstances and following consultation with your professional advisors. The risks in this section are not, and should not be considered to be or relied on as, an exhaustive list of the risks relevant to an investment in Avecho. The risks are general in nature and regard has not been had to the investment objectives, financial situation, tax position or particular needs of any investor.

RISKS

Commercial risk

The development and commercialisation of Avecho's technology is subject to an inherent risk of failure, including the possibility that the products developed by Avecho may fail to demonstrate any material benefit or advancement in brain optimisation or mental health well being, be uncommercial to market or otherwise not commercially exploitable, or fail to achieve the support of physicians, patients or the wider medical industry.

Financial risk

There is uncertainty surrounding the future financial performance of Avecho. Avecho's ability to operate with a profit in the future will depend in part on its ability to successfully commercialise its products. Other factors that will determine Avecho's profitability are its ability to manage costs, execute development and growth strategies, penetrate emerging markets and comply with its debt obligations.

Future capital needs

It may be necessary for Avecho to raise additional funds in order to undertake further product development or fund other needs which arise. There is no assurance that such funding will be available to Avecho in the future or that it will be available on acceptable terms.

Competition risk

The technological advancement and mental health awareness industries are competitive and are constantly subject to change. Some of Avecho's competitors have substantially greater financial and human resources than Avecho. Consequently, there is a possibility that other parties will develop new software and service offerings which will compete with or supersede Avecho's products and intellectual property, with resulting adverse effects on Avecho's performance and profitability.

Intellectual property risk

Avecho's success will depend on its ability to protect its intellectual property while operating without infringing the property rights of third parties or having third parties circumvent Avecho's proprietary rights. Such intellectual property may not be capable of being legally protected and may be subject of an unauthorised disclosure or unlawfully infringed upon by third parties. Avecho may incur substantial costs in asserting or defending its intellectual property rights.

Loss or theft of data

Avecho's products involve the storage of its users' confidential, personal and sensitive information. Avecho's business could be materially disrupted by privacy breaches which may impact the security of client information / data, unauthorised hacking, disruption, general misuse or unauthorised disclosure of a user's personal data. While Avecho undertakes measures to prevent and detect the occurrence of such privacy breaches, there is a risk that such measures may not be adequate. Any data breach will need to be reported to the relevant authorities and may cause substantial reputational and financial damage to the Company.

QUESTIONS WELCOME

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