

ASX Announcement

30 May 2022

Chair's Address & CEO Presentation

Melbourne, Australia, 30 May 2022: 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 30 May 2022.

- ENDS -

This announcement is authorised for release by the Board of Directors of Avecho Biotechnology Limited.

Investor + General Enquiries

Ms Melanie Leydin
Company Secretary
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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 major projects include delivering TPM® enhanced injectable, oral and topical products for the human health market and is also developing TPM® to enhance the 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.

No representation, warranty or assurance (express or implied) is given or made by Avecho that the forward-looking statements contained in these materials 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 these materials 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.

Chair's Address

Dear Shareholders,

I am pleased to share a Company update on behalf of [Avecho Biotechnology Limited](#) to coincide with Company's Annual General Meeting (AGM) today.

The last year has been defined by significant progress for our cannabinoid (CBD) programs. Our oral CBD capsule completed its Phase I clinical trial; our topical CBD gel showed promise in a Phase II osteoarthritis trial; and we executed our first licensing and partnership agreements in the cannabis space for both short and long-term gain.

Right now, our focus remains on developing our oral CBD capsule, including immediate pivotal clinical and regulatory work in order to support a regulatory submission to the TGA. Alongside this, our topical formulation is on track to address novel applications for conditions like osteoarthritis.

Our Company is primed for growth, and we already have strong interest in the CBD product from further potential licensees. We are moving forward, methodically and with great care, to deliver value for our investors.

Key Achievements

> **CBD Capsule: Clear Path to Registration**

This year we have focused on the continued advancement of our CBD TPM® capsule. In December last year, we announced the completion of our Phase I Clinical trial that characterised the absorption profile of CBD from our proprietary capsule. This was a key milestone that now enables progress into our planned **Phase III clinical trial and** will also form a pivotal piece of our **data package** to support the registration of our soft-gel product with the TGA.

> **First Licensing Deal for the CBD TPM capsule**

The completion of our Phase I study triggered an immediate licensing deal for the CBD TPM® capsule in the US. Perland Pharma (previously named Medterra Pharma) licensed the product for use in arthritis indications. Perland will fund all clinical development in the indication, with studies scheduled to begin this year. This partnership will place the CBD capsule before the FDA and provides Avecho with potential pathway for another indication that we did not intend to immediately pursue ourselves. This is a model we intend to explore further, and we are in ongoing discussions with several additional potential licensees.

> **Recreational Cannabis: Immediate Revenue**

The work we have done on the pharmaceutical development of cannabinoids, has generated interest and a subsequent first deal for the use of TPM® in the broader cannabis market. We recently entered into a licensing and supply agreement with US-based company, Team SAAS LLC, to use our TPM® technology to develop and commercialise a unique cannabis distillate for use in consumer cannabis products in the US. Recreational cannabis **represents a large and lucrative market**, with sales of cannabis-related products totalling US\$17.5B in 2020. With little in the way of product differentiation, it is hoped that TPM® sales into the space could be significant and provide a valuable source of future revenue to support Avecho's ongoing research and development (R&D).

> **Focused Research for New Indications**

In addition to commercial partnerships, Avecho has also established important research collaborations as it explores new cannabinoid dosage forms. In collaboration with the Lambert Initiative, Avecho completed a successful **Phase II clinical trial that** examined whether CBD could provide relief from symptoms of osteoarthritis. The results of this early study were very positive and justify further clinical development of topical cannabinoid gels using TPM®.

Avecho's work on cannabinoids continues to build value for the Company and these programs will remain the focus for our investment moving forward. We hope that the next year will see even further advancements.

Financial Outlook

Avecho has a secure balance sheet with sufficient resources to progress all the work and near-term milestones. This will be further supported by our manufacturing program and commercial partnerships, which are principally focused on sustainable revenue generation. Our Company also remains committed to using cash resources to invest in research and development, and licensing activities.

Conclusion

On behalf of the Avecho team I would like to express our gratitude for your continued support. We are on track to drive promising commercial activity in the CBD space in the year ahead – having delineated clear goal posts with key regulators and backing from reputable commercial partners.

Thank you for your continued support and we look forward to keeping you updated with our progress.

Dr Greg Collier



Avecho Biotechnology Limited Chairman

ANNUAL GENERAL MEETING

30TH MAY 2022

Avecho

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.

FAST FACTS

- Building proprietary **differentiated cannabinoid** products **with TPM® delivery technology**
- First **75 mg CBD capsule completed** with Catalent, USA (May 2021)
- **Phase I PK study completed** (Dec 2021) – characterised absorption
- **Australian Phase III trial** for an insomnia indication to start 2022
- Targeting over-the-counter **registration in Australia**, followed by ROW
- **Licenses signed** for CBD capsule and TPM in overseas markets (Dec 21-Feb 22).
- **Revenue generating** manufacturing business to support R&D



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



LEGACY PROGRAMS



HUMAN HEALTH

- Multiple potential licensees undertaking due diligence.
- Multiple assets being considered
- Minimal investment moving forward



ANIMAL HEALTH

- AB Vista will not continue with TPM®
 - AB Vista has its own internal product under development.
 - Study showed feeds containing TPM improve diarrhea in pigs, but not significantly better than internal product under development.
- Still waiting EFSA decision

PHARMACEUTICAL CBD CAPSULE



CANNABINOIDS AS MEDICINE

Medicinal cannabis extracts are being legalized around the world

Some markets are also 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

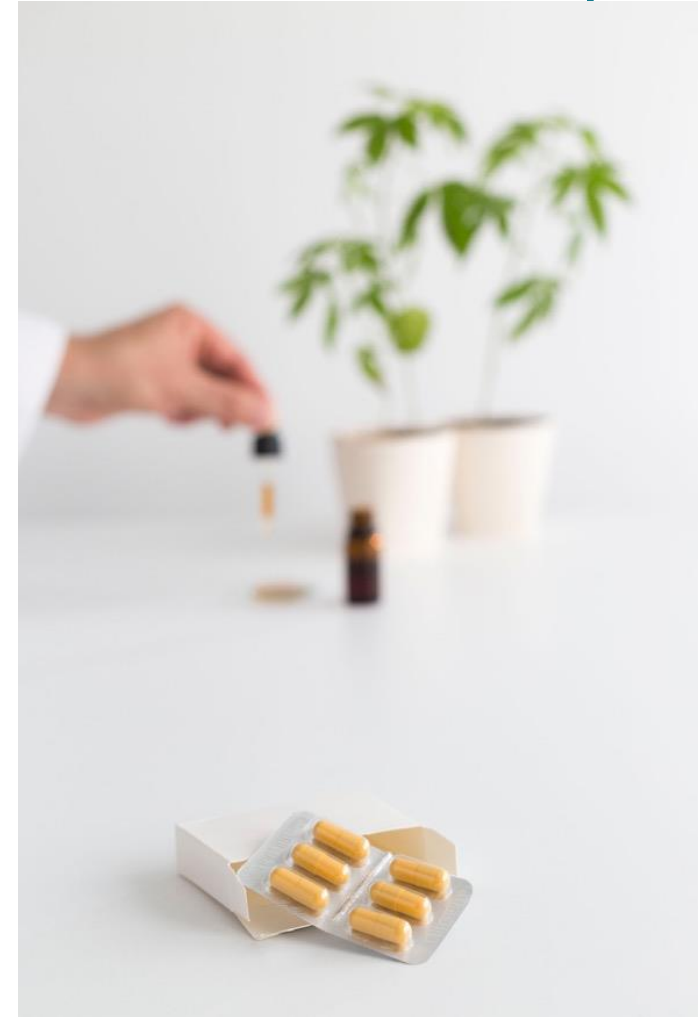
Cannabinoids are oil soluble molecules with low solubility in water

Oil soluble molecules have poor oral bioavailability, which is also true for cannabinoids (3-8% absorbed)

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

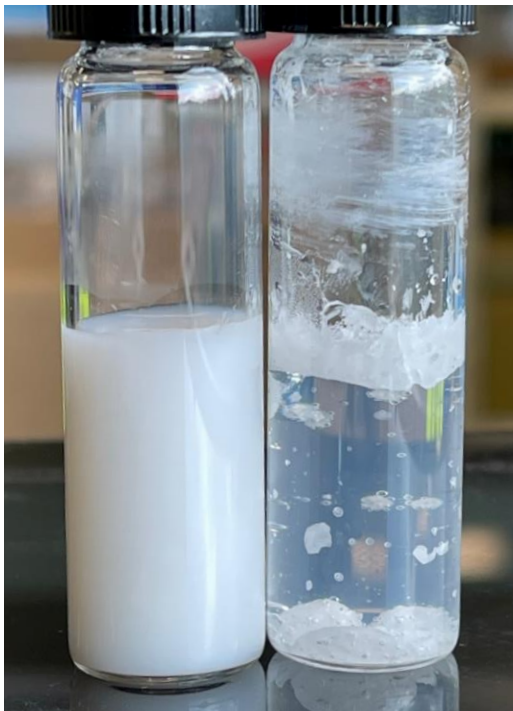
Increasing cannabinoid bioavailability has become a focus for many laboratories around the world, as increasing bioavailability can allow;

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



AVECHO'S TPM[®] INCREASES CANNABINOID ABSORPTION

CBD Solubility

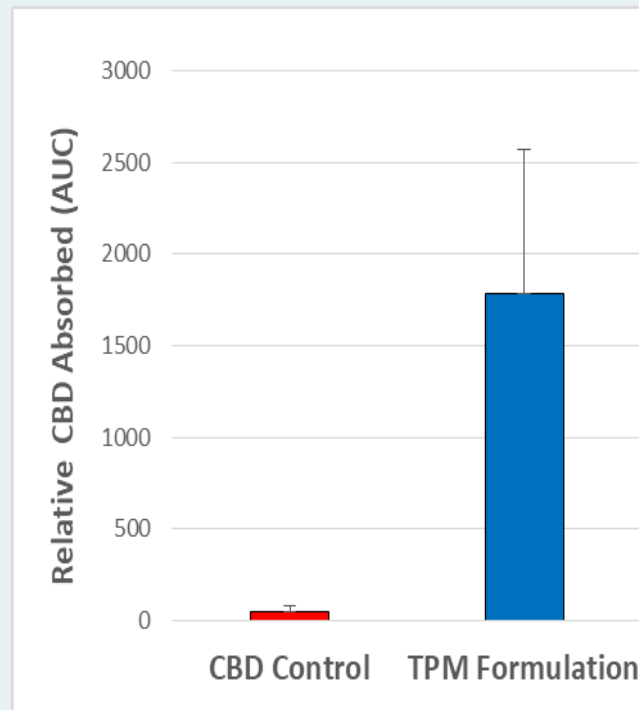


With TPM

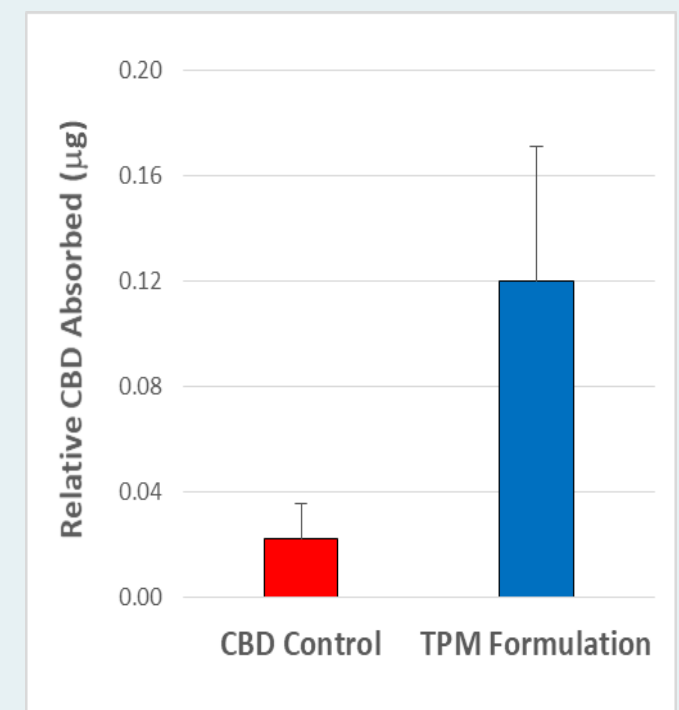
Without TPM



Increased oral absorption



Increased topical absorption



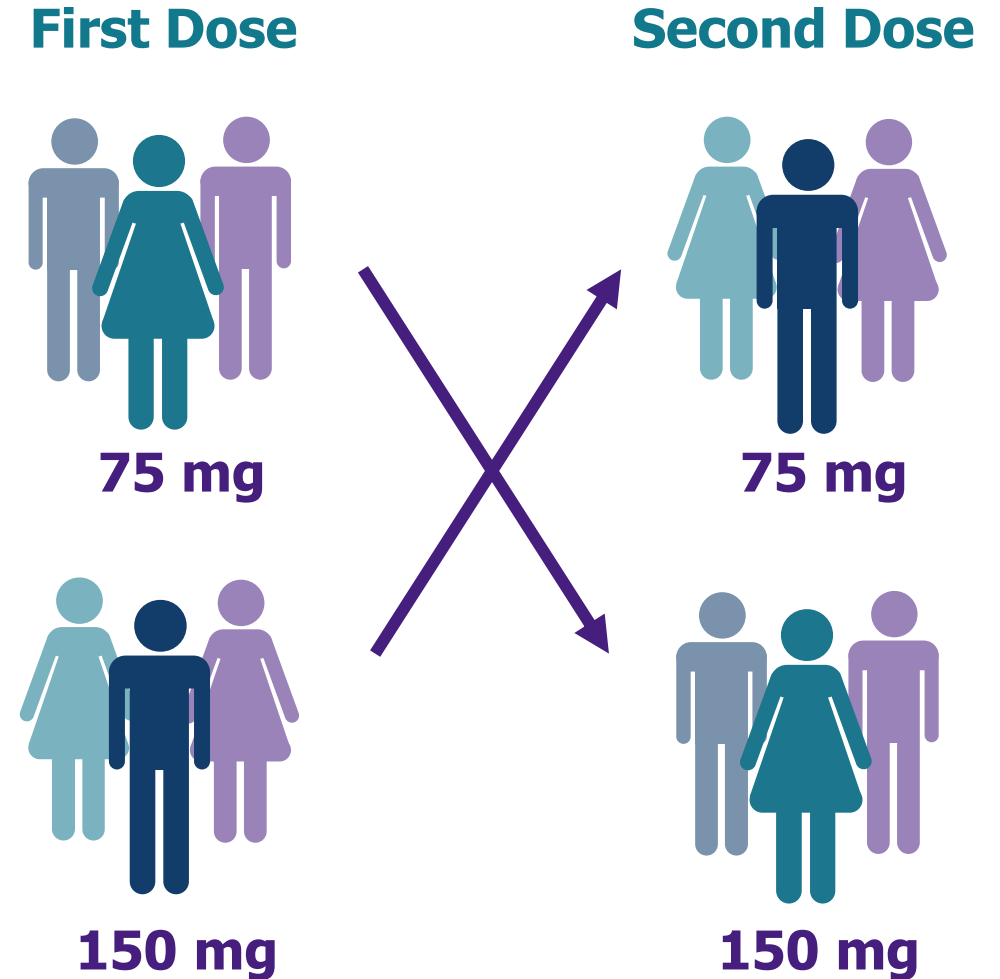
PHARMACEUTICAL CBD TPM CAPSULE COMPLETE

- Formulations developed over the last 2 years; increase CBD absorption in animal models
- Capsule finalised at Catalent, USA (May 21)
- 75 mg of ultra-pure, synthetic CBD (Purisys) per capsule
- Product shows good stability (ongoing).
- 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.
- Product seeking TGA approval as an over-the-counter (S3) medicine.
- International PCT patent applications filed to protect formulation



PHASE I TRIAL: CHARACTERISING CBD ABSORPTION

- Demonstrated single dose pharmacokinetic (PK) profiles of 75 mg and 150 mg oral CBD capsule - Primary objective
- Demonstrated safety and tolerability, in addition to absorption of TPM - Secondary objectives
- Study results will be a vital part of a TGA submission dossier and future product label
- Study results will form an important part of BD and licensing discussions



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



DEVELOPMENT PROGRAM (2022-23)

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/Q4 2022**)
- Complete CMC dossier for use in registration dossier (**2023**)

Phase III sleep indication

- Study design being finalised
- Service providers being actively identified and engaged
- Ethics approval expected (**Q3 2022**)
- Scaled-up clinical supply available for dosing (**Q3/Q4 2022**)

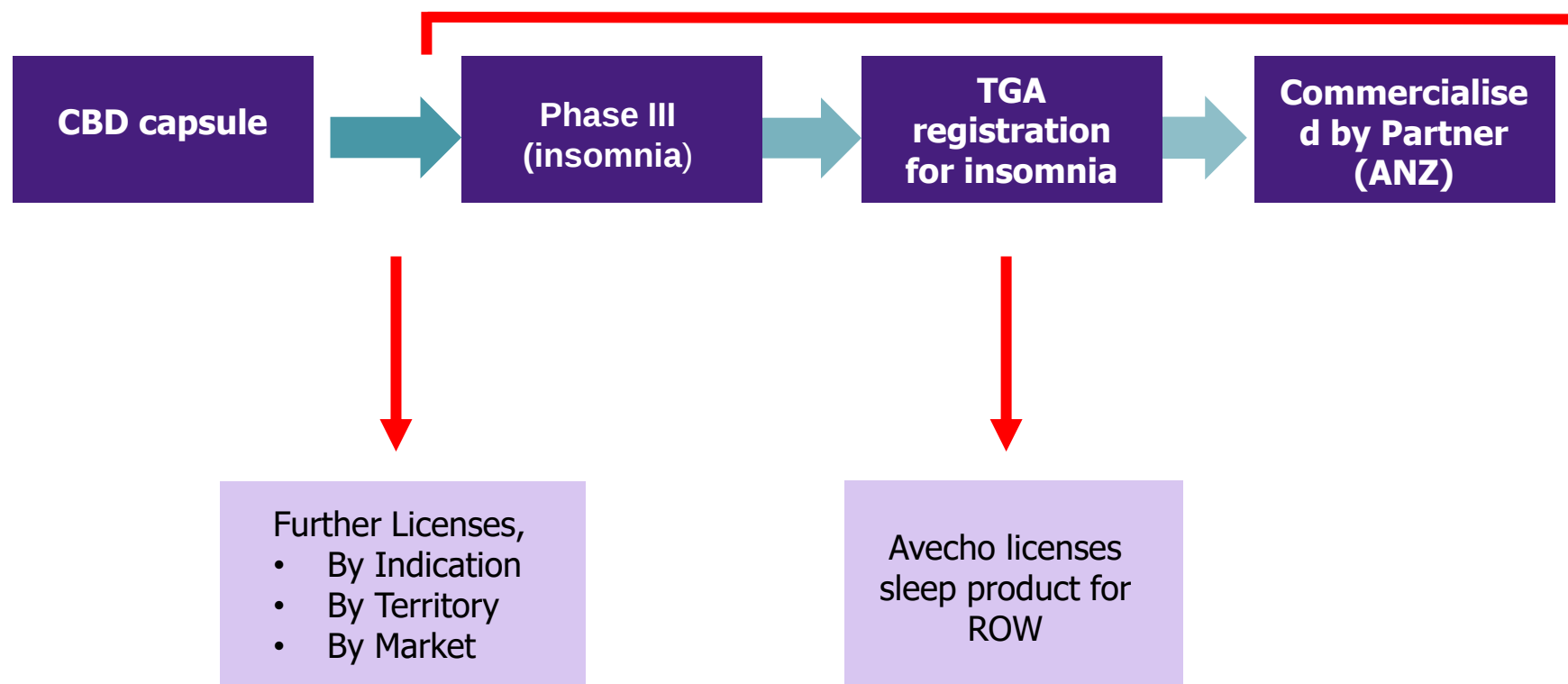
Regulatory Submission – Compile and submit dossier to TGA (**2023**)

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

Finalised trial design and timing will be the subject of a future communication in the coming months

MAXIMISING VALUE FROM THE CBD PRODUCT DEVELOPMENT

REMAINING DEVELOPMENT



Global medical cannabis market
~\$7.8 Bn in 2020;
expected to be
\$30-50 Bn by 2027

Global cannabis market ~20 Bn (USD) in 2021;
expected to be 90 Bn (USD) by 2026

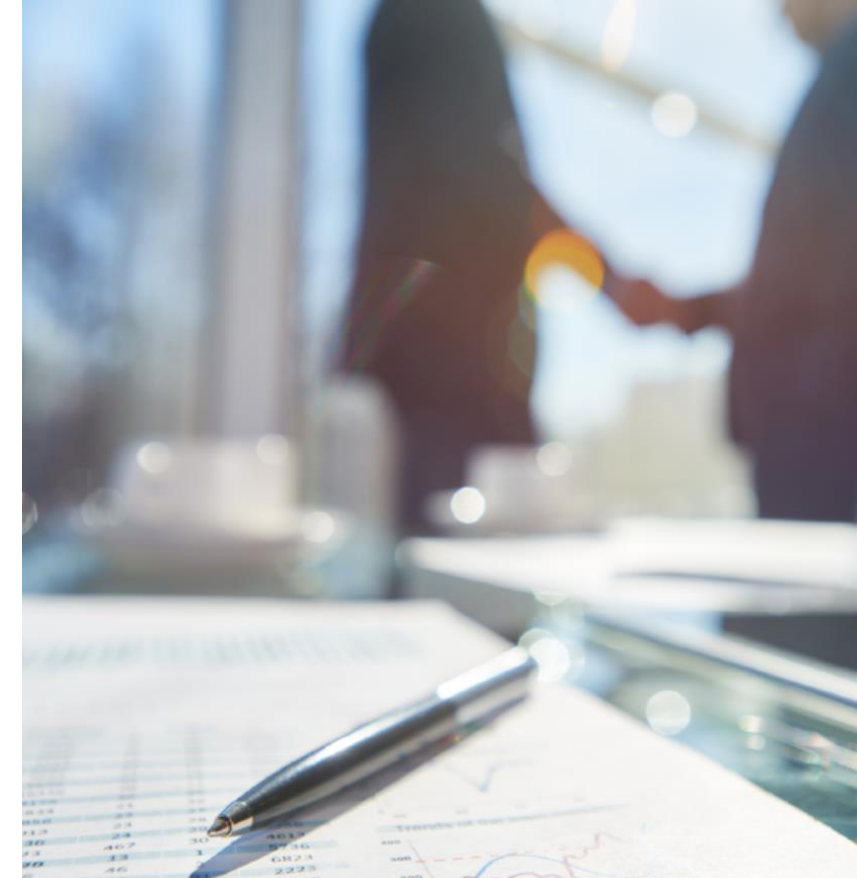
CANNABINOID DEALS ALREADY SIGNED

CBD capsule for arthritis

- CBD capsule licensed (Dec 2021) for arthritis indication (osteo and rheumatoid arthritis), to Perland (Mediterra 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 2022

TPM for the US Recreational Cannabis Space

- TPM Licensed (Feb 2022) for specific use in the US recreational cannabis market to Team SAAS
- Team SAAS who will supply a TPM cannabis distillate for use in the manufacture of cannabis gummies
- Team SAAS will purchase TPM from Avecho with an additional 50:50 profit split.



More deals to come

NEW DOSAGE FORMS



TOPICAL CBD TPM GEL: PHASE II OSTEOARTHRITIS TRIAL

Avecho has completed a Phase II clinical trial in collaboration with the Lambert Initiative testing a topical CBD gel in patients suffering osteoarthritis of the hand.

- N=15 subjects applied a topical CBD gel to painful fingers/thumbs each day for 4 weeks
- Pain scores and measurements of grip strength were recorded each day
- Functional measurements were recorded once per week.

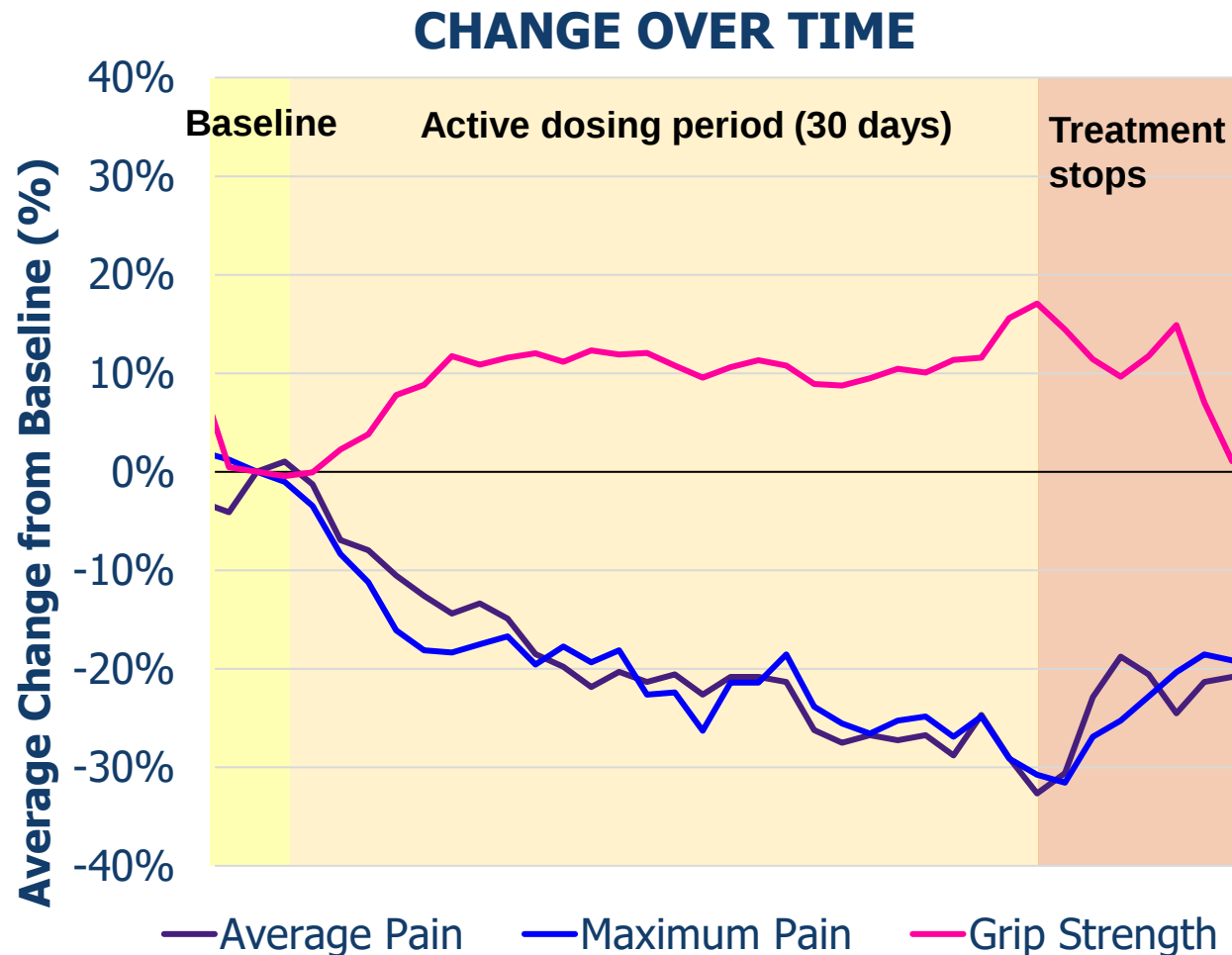


CBD from topical vehicles developed for commercial TPM® formulations (ie. Voveran TPM) has 3-5x increase in dermal absorption

PHASE II: TOPICAL CBD TPM IMPROVES PAIN AND GRIP STRENGTH

- “Average Pain” significantly decreased over the study period ($p < 0.001$)
- “Maximum Pain” significantly decreased over the study period ($p < 0.001$)
- Grip Strength significantly increased over the study period ($p < 0.001$)
- Study results being presented at the International Cannabinoid Research Society Symposium in June by the Lambert

**Larger Phase II studies
planned with the Lambert
Initiative**



GROWING PORTFOLIO OF DIFFERENTIATED CANNABINOID PRODUCTS

Product	Therapeutic Area	Partner (Geography)	Preclinical	Phase I	Phase II or Observation al 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)					
CBD Oil	Miscellaneous	Comp. pharmacy					
CBD Topical Gel	Miscellaneous	Comp pharmacy					



COMPANY OVERVIEW

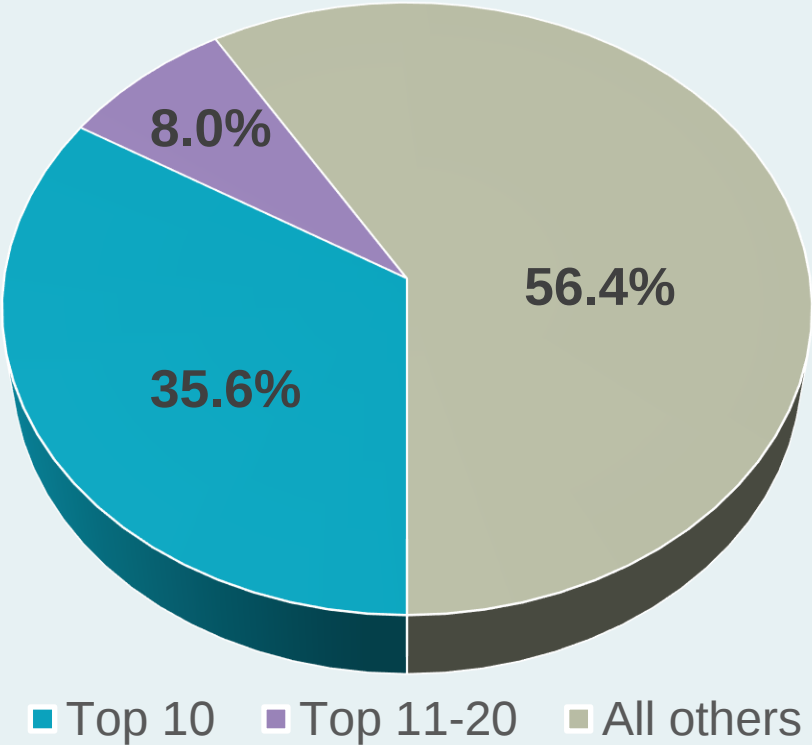


COMPANY SNAPSHOT

Cash	\$2.44M ¹
R&D tax credit	+ \$1M
As of 26 th May;	
Shares	1,838M
Market cap	\$31.2M
Options/Performance Rights	217.3M

¹ Quarter ending 31 March 2022

Holdings by Top 20 Shareholders



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

- 20+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



NEWS 2022

- **MANUFACTURING**; complete scale-up of the CBD capsule, CMC dossier, registration batches
- **PHASE III INSOMNIA PROGRAM** using oral CBD capsule; complete study design, initiate program for insomnia indication
- Further **PHASE II OSTEOARTHRITIS** trial using topical gel
- Commercial **PARTNERING/LICENSING** opportunities; new markets, new territories, new indications
- New **DOSAGE FORMS/NEW CANNABINOIDS**



QUESTIONS WELCOME

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