



## ASX RELEASE

3 April 2023

### AVECHO BIOTECHNOLOGY CONDUCTS ENTITLEMENT OFFER TO RAISE \$11M TO FUND PIVOTAL PHASE III CLINICAL TRIAL

#### Highlights:

- *Entitlement Offer to Eligible Shareholders to raise up to approximately A\$11 million (before costs), on the basis of 1 New Share for every 1 existing share held by Eligible Shareholders on the Record Date, at an issue price of A\$0.006 per Share with 3 free attaching New Options for every 2 New Shares subscribed for.*
- *Funds raised under the Entitlement Offer will be used to provide funds for conducting a Phase III clinical trial in respect of the Company's proprietary TPM enhanced CBD soft-gel capsule to manage the symptoms of insomnia, associated manufacturing activities for the clinical trial and costs of the Entitlement Offer.*

**Melbourne, Australia, 3 April 2023:** Avecho Biotechnology Limited (ACN 056 482 403) (ASX:AVE) (**Avecho** or **Company**) has today announced that it is undertaking a capital raise seeking approximately \$11 million. Proceeds from the raise will be used to fund a pivotal Phase 3 clinical trial designed to test the Company's proprietary CBD soft-gel capsule for the treatment of insomnia.

Avecho has developed the TPM® enhanced CBD soft-gel capsule with increased absorption over the last three years, proceeding through formulation development and optimisation, chemistry manufacturing and controls, and a Phase I clinical trial characterising the drug absorption from the product in humans.

The Company will now commence a pivotal randomized, placebo-controlled Phase 3 clinical trial, designed with leading clinical sleep researchers in Australia and internationally. The Study will be a rigorous investigation of the effectiveness of our proprietary CBD soft-gel capsule in the treatment of insomnia, targeting 540 patients across three treatment groups to compare nightly CBD doses of 75 and 150 mg CBD with placebo over an 8-week dosing period.

The Study is the last major piece of data required to support a future TGA submission. The TGA has not previously assessed CBD in a submission package for pharmaceutical approval – similarly, no regulatory agency in the world has approved CBD for an insomnia indication. Consequently, the planned study has been designed to maximise the chance of a successful Phase III trial, minimise potential reasons for the TGA to reject our future submission, and augment the chance of negotiating significant commercial deals with leading international pharmaceutical companies.

The entitlement offer announced today will allow the Company to drive the Phase 3 trial toward completion, which will be a significant inflection point for the Company.

#### Capital Raising

The raise is a non-renounceable entitlement offer of 1 new fully paid ordinary share (**New Share**) for every 1 existing share held by eligible shareholders on the record date (being 7.00pm (AEST) on Thursday, 6 April 2023) (**Record Date**), at an issue price of \$0.006 per New Share to raise up to approximately \$11 million (before costs) (**Entitlement Offer**).

Participants in the Entitlement Offer will also be issued 3 free attaching options, with an exercise price of \$0.012 each and expiring 3 years from their issue date (**New Option**) for every 2 New Shares subscribed under the Entitlement Offer.

The Offer Price of \$0.006 per New Share represents a:

- 33.33% discount to last close of A\$0.009; and
- 26.83% discount to the 15 day volume weighted average price of shares trading on ASX of A\$0.0082,

at the close of trading on Friday, 31 March 2023 being the last trading day prior to the announcement of the Entitlement Offer. Peak Asset Management and CPS Capital are joint lead managers to the Entitlement Offer. The Entitlement Offer is not underwritten.

The entitlements are non-renounceable and will not be tradeable on ASX or otherwise transferable. Eligible shareholders who do not take up their entitlements will not receive any value for those entitlements that they do not take up. Shareholders who are not eligible to receive entitlements will not receive any value for the entitlements they would have received had they been eligible.

Avecho will notify shareholders as to whether they are eligible to participate in the Entitlement Offer in accordance with ASX Listing Rule 7.7.1(b). The Entitlement Offer is being conducted under a Prospectus, which has been lodged with the Australian Securities and Investments Commission today.

The Entitlement Offer is expected to open on Thursday, 13 April 2023. Eligible shareholders will receive a copy of the Prospectus including a personalised entitlement and acceptance form which will provide further details of how to participate in the Entitlement Offer.

Should you have any queries in relation to the Entitlement Offer, please do not hesitate to call the offer information line on 1300 850 505 (within Australia) or +61 3 9415 5000 (outside Australia) between 8.30am and 5.00pm (AEST) Monday to Friday during the offer period.

Additional information including a Q&A and video summary will be available at the Avecho Investor Hub at <https://ave.freshamplify.com/welcome>. You may also ask questions to us directly on the Investor Hub. We encourage shareholders to sign up to the Investor Hub.

### **Investor webinar**

Avecho is pleased to invite shareholders, investors and interested parties to an investor webinar and Q&A with CEO, Dr Paul Gavin, to discuss the Company's investment proposition and rationale for the Entitlement Offer. The webinar will be held on Tuesday, 4 April at 2pm (Melbourne Time).

Register for the webinar at the following link:  
[https://us02web.zoom.us/webinar/register/WN\\_TSujLgLfQiWGefp-l5B1HA](https://us02web.zoom.us/webinar/register/WN_TSujLgLfQiWGefp-l5B1HA)

For the Q&A session, investors are invited to send questions in advance to: [matt@nwrcommunications.com.au](mailto:matt@nwrcommunications.com.au). After registering, you will receive a confirmation email containing information about joining the webinar as well as dial-in details for those that would prefer to join by phone. A recording will be available at the above link shortly after the conclusion of the live session.

### **Use of Funds**

The funds raised under the Entitlement Offer will be used for:

- manufacturing activities associated with the production of test articles to be used in the Phase III clinical trial, in addition to formal stability studies required for a future regulatory submission;
- the conduct of a pivotal randomised, placebo-controlled Phase III clinical trial testing the Company's proprietary CBD soft-gel capsule's ability to manage the symptoms of insomnia; and
- costs of the Entitlement Offer.

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-imbursalment 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.

Avecho CEO, Dr Paul Gavin, said *“For any biotechnology company aspiring to bring a product to the market, Phase 3 is the penultimate step in the clinical development process before seeking regulatory approval, and we’re excited to be on the cusp of this for our CBD TPM capsule. We’ve been particularly strategic over the last 12 months to design this trial to account for the placebo effect, something that this type of sleep trial is susceptible to and was not factored in by others in Australia who have taken CBD products into Phase 3 trials to date. The work we’ve put into carefully designing the trial will give Avecho the best chance of a successful outcome, and the funds we’re aiming to raise in this round will allow us to pursue that unimpeded. It’s an outstanding opportunity for the Company, both within Australia but also for the potential to take this product and target further geographies, markets, and indications.”*

## Key dates

Summary of key dates	Date/time
Entitlement Offer announced	Monday, 3 April 2023
Ex-date for Entitlement Offer	Wednesday, 5 April 2023
Record date for Entitlement Offer	7.00pm (AEST) on Thursday, 6 April 2023
Entitlement Offer opens and Prospectus dispatched	Thursday, 13 April 2023
Entitlement Offer closes	5:00pm (AEST) on Wednesday, 3 May 2023
Shares quoted on a deferred settlement basis	Thursday, 4 May 2023
Announce results of Entitlement Offer to ASX Entitlement Offer settlement date	Tuesday, 9 May 2023
Allotment and issue of New Shares and New Options	Before noon on Wednesday, 10 May 2023
Commencement of trading of New Shares and New Options	Thursday, 11 May 2023

All dates are indicative only and subject to change. The Company reserves the right to withdraw or vary the timetable without notice, subject to compliance with the ASX listing rules.

This release has been approved by the board of directors of the Company.

## For more information contact:

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## About Avecho Limited (ASX: AVE)

Avecho Biotechnology Limited develops and commercializes innovative Human and Animal Health products using its proprietary drug delivery system called Tocopheryl Phosphate Mixture (TPM®). TPM® is delivered 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 - <https://avecho.com.au/>

## **Important Notices**

### **Not an offer in the United States**

This announcement has been prepared for publication in Australia and may not be released to US wire services or distributed in the United States. This announcement does not constitute an offer to sell, or a solicitation of an offer to buy, securities in the United States or in any other jurisdiction in which such an offer would be unlawful. The New Shares have not been, and will not be registered under the US Securities Act of 1933, as amended (US Securities Act) or the securities laws of any state or other jurisdiction of the United States. Accordingly, the New Shares may not be offered or sold, directly or indirectly, in the United States unless they have been registered under the US Securities Act (which Avecho has no obligation or intention to do or procure) or are offered and sold in a transaction exempt from, or not subject to, the registration requirements of the US Securities Act and any applicable U.S. state securities laws.

The information in this announcement is of general background and does not purport to be complete. It should be read in conjunction with Avecho's other periodic and continuous disclosure announcements lodged with ASX Limited, which are available at [www.asx.com.au](http://www.asx.com.au).

### **Forward looking statements**

This announcement contains certain "forward-looking statements". The words "expect", "anticipate", "estimate", "intend", "believe", "guidance", "should", "could", "may", "will", "predict", "plan" and other similar expressions are intended to identify forward-looking statements. Indications of, and guidance on, future earnings and financial position and performance are also forward-looking statements. Forward-looking statements, opinions and estimates provided in this announcement are based on assumptions and contingencies that are subject to change without notice and involve known and unknown risks and uncertainties and other factors that are beyond the control of Avecho, its directors and management. This includes statements about market and industry trends, which are based on interpretations of current market conditions. Forward-looking statements are provided as a general guide only and should not be relied upon as an indication or guarantee of future performance. Actual results, performance or achievements may differ materially from those expressed or implied in such statements and any projections and assumptions on which these statements are based.

These statements may assume the success of Avecho's business strategies. The success of any of those strategies will be realised in the period for which the forward-looking statement may have been prepared or otherwise. Readers are cautioned not to place undue reliance on forward-looking statements and except as required by law or regulation, none of Avecho, its representatives or advisers assumes any obligation to update these forward-looking statements. No representation or warranty, express or implied, is made as to the accuracy, likelihood of achievement or reasonableness of any forecasts, prospects, returns or statements in relation to future matters contained in this announcement. The forward-looking statements are based on information available to Avecho as at the date of this announcement. Except as required by law or regulation (including the ASX Listing Rules), none of Avecho, its representatives or advisers undertakes any obligation to provide any additional or updated information whether as a result of a change in expectations or assumptions, new information, future events or results or otherwise. Indications of, and guidance or outlook on, future earnings or financial position or performance are also forward-looking statements.

### **General**

This announcement is subject to the same "Disclaimers" that appear on slide 2 of the investor presentation released to the ASX today with any necessary contextual changes. Investors should make and rely upon their own enquiries before deciding to acquire or deal in Avecho's securities.