ASX Announcement

28 April 2023

Avecho Quarterly Activities Report and Appendix 4C

Key Highlights

- Pivotal Phase III clinical trial ready to commence – a major study, the largest of its kind in Australia, to test Avecho's proprietary CBD soft-gel capsule for the treatment of insomnia.
- Entitlement Offer to shareholders to raise ~$11M in progress.
- Expansion to key commercial and research partnerships with up to seven clinical trials in 2023, including internationally recognised work underway with the Lambert Initiative.
- Cannabinoid portfolio expanded to include edible products.

Melbourne, **Australia, 28 April 2023**- Avecho Biotechnology Limited (ASX: AVE) ("Avecho" or the "Company"), focused on developing and commercialising innovative products using its proprietary Tocopheryl Phosphate Mixture (TPM®) drug delivery system, is pleased to release its Quarterly Activities Report and Appendix 4C for the quarter ended 31 March 2023.

Avecho CEO Dr Paul Gavin said:
"We are pleased to be entering Phase III of the clinical development process of our TPM®-enhanced CBD soft-gel capsule – a crucial step towards regulatory approval. We've spent the last 12 months planning our sleep study, which has been strategically designed to mitigate the placebo effect observed by our peers, and to give our Company the best chance at success. This will be a significant milestone for Avecho in Australia, but also has the potential to open doors to new markets and indications globally.

The ongoing capital raising is intended to fund the Phase III trial, and we feel this provides an excellent opportunity to invest at the Phase III stage where valuations normally sit much higher. We're very confident that a successful trial outcome will consequently deliver outstanding value for prospective and existing shareholders."

Planning for Phase III trial of CBD soft-gel capsule

Avecho is committed to researching how cannabidiol ("CBD") can improve sleep. The Company has reached the final stages of preparation for a pivotal Phase III study investigating the efficacy of its proprietary CBD soft-gel capsule in the treatment of insomnia, which received formal ethics approval in December 2022.

This study is set to be the largest randomised, placebo-controlled trial to be conducted in Australia to support the registration of CBD as an over-the-counter ("OTC") medicine with the Therapeutic Goods Administration ("TGA"). The clinical trial has been designed to generate clinical evidence that can be utilised to support product registration with key global regulatory bodies, including the TGA, US Food and Drug Administration, and European Medicines Agency.

Earlier this year, the importance of clinical trial design was demonstrated when two of Avecho's peers failed to achieve a statistically significant difference between a placebo and CBD in a Phase III trial evaluating low doses of CBD for 'sleep disturbance'. Avecho's Phase III trial for insomnia is differentiated by various factors:

1. There are measures in place to limit the potential damage caused by the placebo effect.
2. The inclusion criteria for patients are stricter than those of other registered CBD sleep studies, with higher starting insomnia scores.

3. The trial will be conducted over a longer dosing period, maximising the timeframe over which CBD can demonstrate an effect.
4. The study will be exploring higher doses of CBD than those used in some other studies, investigating daily doses of up to 150mg per day.

This trial is larger than currently registered CBD studies, with 540 participants to be dosed as part of the study. An interim analysis is planned after 300 patients to confirm the number of subjects required to complete the trial. The study will be conducted at up to 10 sites around Australia, with Monash Medical Centre in Melbourne as the lead site under the supervision of Principal Investigator, Associate Professor Darren Mansfield, Deputy Director of Monash Health.

Recent media, including nationwide coverage on Channel 7 News (https://youtu.be/lO3VzD0k9RA), about the upcoming study generated significant public interest in participation. Feedback highlights the prevalence of insomnia in the community and the urgent need for new treatment options. Expressions of interest regarding participation in the study can be registered at the following link (cbdinsomniastudy.com).

Entitlement Offer to Shareholders to fund the Phase III trial

Post quarter end, the Company announced it was undertaking a capital raise seeking approximately A$11 million. Proceeds from the raise will be used to fund the pivotal Phase III clinical trial designed to test the Company's proprietary CBD soft-gel capsule for the treatment of insomnia.

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 the 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.

Additional information including a Q&A and video summary will be available at the Avecho Investor Hub – you may join by visiting https://ave.freshamplify.com/welcome. You may also direct questions to the Company's senior management team directly via the Investor Hub.

At the conclusion of the Entitlement Offer to eligible shareholders, Avecho has engaged CPS Capital and Peak Asset Management as Joint Lead Managers to place the shortfall. Shortfall will be placed at the same terms of the Entitlement Offer.

Partnered programs with third parties

Avecho has previously collaborated with the Lambert Initiative on a successful Phase II clinical trial examining the use of a topical CBD TPM® gel for the treatment of osteoarthritis of the fingers and hands. While only small, the study showed significant improvements in both pain and grip strength after topical

application of the CBD TPM® product. Results from this study were presented by Lambert Initiative researchers at the International Cannabinoid Research Society Symposium on the Cannabinoids in June 2022 and are currently being written up for publication. This study has formed the basis for a larger, randomised, placebo-controlled topical CBD trial currently being planned with the Lambert Initiative in 2023. The protocol for this study is currently being finalised.

In February 2023, Avecho announced its collaboration with the Lambert Initiative would expand beyond the topical cannabinoid products. While Avecho focuses its efforts on its pivotal Phase III clinical trial testing its CBD soft-gel capsule in an insomnia indication, the Lambert Initiative trials will test its oral CBD product on a series of novel candidate indications not previously associated with CBD therapy. These candidate indications have emerged from pre-clinical and early-stage clinical studies conducted by Lambert Initiative researchers and their colleagues, and represent attractive indications for future CBD products registered as OTC medicines with the TGA.

In December 2022, Avecho announced a development agreement with NYSE-listed global consumer packaged goods business Perrigo Company plc (NYSE: PRGO), in a deal that will focus on development of a topical TPM®-enhanced ibuprofen gel for the US market. Perrigo is planning to conduct a clinical trial in a pain-related indication using the ibuprofen TPM® gel in 2023. Positive results from this trial would trigger a licensing agreement and continued development of the product for FDA registration, which if successful would give the product the potential to be the first topical ibuprofen product approved in the US.

Avecho is managing the manufacture of the Ibuprofen TPM® product in Australia using a third party GMP contract manufacturer. During Q1 CY23, the manufacturing and analytical methods for the Ibuprofen TPM® formulation were established at the CMO, with initial manufacturing runs to commence shortly.

In January 2023, Avecho announced that New York-based global biopharmaceutical company Athenex had submitted Avecho's TPM®-enhanced phytonadione injectable product to the FDA for feedback via a pre-IND meeting request. FDA feedback will determine the remaining development work required to support a future product registration.

In total, Avecho's products will be used in seven clinical trials throughout 2023. These include the pivotal Phase III insomnia trial, the Perland osteoarthritis study, and two new Lambert Initiative trials which will all use the oral CBD soft-gel capsule. In addition, Perrigo's pain study will use topical ibuprofen, and Avecho will be collaborating with the Lambert Initiative to examine the use of topical CBD and CBG for osteoarthritis of the hand.

Expanding cannabinoid portfolio

Over the last three years, Avecho has completed formulation development on a series of optimised CBD dosage forms, both oral and topical, that demonstrate increased CBD absorption. By the conclusion of CY2022, the Company had replaced CBD in these products with tetrahydrocannabinol, cannabigerol ("CBG"), cannabichromene, and cannabinol, the other major cannabinoids currently being investigated around the world. These products are now proceeding through ongoing stability and will be the focus of future programs and partnering arrangements. The topical CBG product will be tested in a Phase II clinical trial with the Lambert Initiative this year.

In addition, the Company has spent much of this quarter optimising a new dosage form, cannabinoid edibles. While the company has previously announced a licensing arrangement for the use of TPM® in a cannabis distillate to be used in recreational edibles, Avecho wanted to optimise the manufacture and composition of TPM® gummies to maximise cannabinoid absorption. This work has been conducted in collaboration with a US gummy manufacturer.

Prototypes developed at Avecho have already shown increased rate of onset, higher magnitude of absorption and longer duration. Work on these products is ongoing, but they are expected to be of value

to both the medicinal and recreational cannabis markets. The Company will provide further updates on these prototypes as the work continues.

Corporate

During the quarter ended 31 March 2023, Avecho had net operating outflow of A$523K, including A$77K invested in R&D activities. Administration and corporate costs were A$10K during the quarter.

At the end of the quarter, the Company held A$924K in cash.

Payments to related parties and their associates during the quarter, as outlined in Section 6 of the accompanying Appendix 4C to this quarterly activities report, were A$171K.

For enquiries, please contact
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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 this announcement 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 AVE that the forward-looking statements contained in this announcement 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, AVE 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 this announcement or any error or omission therefrom.

Subject to any continuing obligation under applicable law or relevant listing rules of the ASX, AVE 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 AVE since the date of the announcement.

Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity	
AVECHO BIOTECHNOLOGY LIMITED	
ABN	**Quarter ended ("current quarter")**
32 056 482 403	31 March 2023

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (3 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(77)	(77)
	(b) product manufacturing and operating costs	(132)	(132)
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs*	(299)	(299)
	(f) administration and corporate costs	(10)	(10)
	(g) patent portfolio costs	(6)	(6)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	1	1
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other (EMDG)	-	-
1.9	**Net cash from / (used in) operating activities**	**(523)**	**(523)**

**A percentage of staff costs are reallocated to payments for research and development.*

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(h) entities	-	-
	(i) businesses	-	-
	(j) property, plant and equipment	-	-
	(k) investments	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 months) $A'000
	(l) intellectual property	-	-
	(m) other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	**Net cash from / (used in) investing activities**	**-**	**-**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other – Payment of principal element of lease liabilities	(21)	(21)
3.10	**Net cash from / (used in) financing activities**	**(21)**	**(21)**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	1,468	1,468
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(523)	(523)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 months) $A'000
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(21)	(21)
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**924**	**924**

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter $A'000	Previous quarter $A'000
5.1	Bank balances	924	924
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**924**	**924**

6.	Payments to related parties of the entity and their associates	Current quarter $A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	(171)
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.

7.	**Financing facilities** *Note: the term "facility' includes all forms of financing arrangements available to the entity.* *Add notes as necessary for an understanding of the sources of finance available to the entity.*	**Total facility amount at quarter end $A'000**	**Amount drawn at quarter end $A'000**
7.1	Loan facilities	-	-
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	**Total financing facilities**	**-**	**-**

7.5	**Unused financing facilities available at quarter end**	**-**

7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.

N/A

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(523)
8.2	Cash and cash equivalents at quarter end (item 4.6)	924
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	924
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	**1.76**

Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.

8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:

8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer: The Company's research and development expenses will increase in the coming quarters as a pivotal human clinical trial commences. This will increase the spend reported in the net operating cash flows.

8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer: The Company announced a capital raise on the 3rd of April. This raise is intended to raise ~$11M to fund the ongoing operations and Phase III clinical trial. The raise will begin as an entitlement offer to shareholders, with any shortfall to be subsequently placed by brokers. The Company is comfortable that this raise will generate sufficient funds to continue its activities.

8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer: Yes, the Company expects to be able to continue its operations and meet its business objectives on the basis as described in answer to question 8.6.2 above

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

Compliance statement

1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.

2 This statement gives a true and fair view of the matters disclosed.

Date: 28 April 2023

Authorised by: By the Board of Avecho Biotechnology Limited
(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.

2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.

3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.

4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [*name of board committee – eg Audit and Risk Committee*]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".

5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.