ASX Announcement

31 January 2024

Avecho Quarterly Activities Report and Appendix 4C

Melbourne, **Australia, 31 January 2024**: Avecho Biotechnology Limited (ASX: AVE) ("Avecho" or the "Company") is pleased to release its Quarterly Activities Report and Appendix 4C for the quarter ended 31 December 2023.

During the quarter, the Company focused on preparations for the pivotal Phase III trial of its proprietary CBD soft gel capsule targeting insomnia, due to commence late Q1 2024. Being the key pillar for Avecho entering the 2024 calendar year, the strategy, planning and opportunity for its CBD soft gel capsule technology is summarised as follows.

PHASE III STUDY DESIGN

Avecho's Phase III trial for its proprietary CBD soft gel capsule has been carefully planned using both the pharmaceutical industry experience of management, global key opinion leaders in the field of sleep medicine and learnings from other insomnia trials conducted around the world.

Participants who meet the required conditions for enrolment will be divided into three treatment groups:

- One receiving a placebo
- One receiving a 75 mg dosage of the CBD capsule
- One receiving a 150mg dosage of the CBD capsule

This randomized, placebo-controlled setup is vital for the trial's credibility and accuracy. Spanning eight weeks, the study diligently monitors patient progress using daily sleep diaries and questionnaires.

It will be conducted across five major cities in Australia, involving 519 participants, thus ensuring a substantial sample size for reliable results.

This large-scale approach, combined with the varied dosage and the rigorous monitoring, is indicative of Avecho's commitment to demonstrating the effectiveness of CBD in treating insomnia. The study's outcomes could significantly contribute to the field of sleep medicine, as insomnia remains a large problem affecting a significant percentage of the population.

TIMELINES TO INTERIM ANALYSIS – A MAJOR CATALYST

The interim analysis in Avecho's Phase III study represents a critical inflection point. Scheduled late calendar 2024, this analysis will evaluate sleep improvements in the three different groups without revealing group identities to the statisticians. This blind assessment is crucial for maintaining objectivity.

Based on the difference in sleep scores recorded for the three treatment groups, statisticians will conduct a formal powering calculation to determine how many more participants are needed to maximise the chance of statistical significance. This adaptive aspect of the study allows for necessary adjustments based on real-time data, maximising the study's potential for success.

If no significant difference in sleep quality is found among the groups, the Company will have the opportunity to halt the study early in order to preserve capital.

The interim analysis, which was not used in previous Phase III CBD trials, is a critical component of Avecho's study that will maximise the chance of a successful outcome in real time, which protecting the Company from additional expenditure if the results do not look positive.

THE DANGER OF THE PLACEBO RESPONSE

In clinical trials, especially in studies focusing on subjective outcomes like sleep quality, the placebo response is a noteworthy challenge. This phenomenon, where patients report improvements after receiving a non-active treatment, can blur the actual effectiveness of the drug under study. In the context of insomnia, where self-assessment is key in gauging treatment success, this issue is particularly pertinent.

Avecho's trial design incorporates specific strategies to mitigate the placebo effect. This precaution underlines the company's proactive approach in ensuring the accuracy and reliability of its study results. Addressing the placebo response head-on is critical for interpreting a drug's true efficacy and can influence patient care and future drug development strategies.

THE OPPORTUNITY FOR AVECHO

Avecho's Phase III study occurs at a pivotal moment, particularly considering Australia's unique regulatory environment that allows OTC registration of pharmaceutical CBD products. This situation presents a significant commercial opportunity, as OTC products can be accessible directly to consumers without prescriptions. With insomnia being a widespread problem and existing treatments having various limitations, Avecho's market entry could fulfill a substantial unmet medical need.

The Company's strategic focus on insomnia leverages the prevalent condition to explore a potentially lucrative market segment. The potential approval of Avecho's CBD product for insomnia by the TGA could set it apart in this emerging market. This not only addresses a major health concern but also positions Avecho to capitalise on the growing demand for alternative, effective sleep aids.

The combination of market dynamics and the regulatory landscape in Australia creates a large opportunity for Avecho in the pharmaceutical CBD sector where other businesses have been unable to succeed.

US BUSINESS DEVELOPMENT

During the quarter, Avecho's CEO dedicated a substantial amount of time to exploring business opportunities within the North America medicinal and recreational cannabis market.

Having developed at an earlier time and with varied dynamics compared with Australia, North America presents unique opportunities for Avecho's technologies. Recognising the dynamic landscape and evolving regulatory environment, Dr Gavin sought to position the Company as a technology leader with various industry experts and potential business partners in the region.

Dr Gavin also travelled to San Francisco for the recent JP Morgan Healthcare week which brings together a range of the leading biotechnology and pharmaceutical groups from around the world.

The meetings and interactions from these business development activities provided a platform to showcase Avecho's expertise, discuss potential collaborations, and explore avenues for strategic partnerships. The Company will update the market as to future material developments arising from these discussions.

CORPORATE

During the quarter ended 31 December 2023, the Company received a sum of ~A$2.4 million, net of transaction fees, from the Tranche 2 Placement capital raise.

The Company held a General Meeting on 9 November 2023 to seek shareholder approval on corporate transactions related to the Placement:

a) The Placement raised ~A$6 million before costs in two tranches:

- ~A$3.2million raised through the issue of ~536 million of fully paid ordinary shares ("AVE Shares") at $0.006 each to professional and sophisticated investors on 8 September 2023; and
- ~A$2.8 million raised through the issue of ~471 million AVE Shares to professional and sophisticated investors (including to directors Mr Matthew Patrick McNamara and Dr Gregory Collier) at $0.006 each on 22 November 2023 following shareholder approval on 9 November 2023. 1,666,666 and 5,833,333 AVE Shares were respectively issued to Mr McNamara and Dr Collier.

b) Quoted Options:

- ~1,499 million quoted Options exercisable at $0.012 (1.2 cents) each and expiring on 10 May 2026 were issued on 22 November 2023 to professional and sophisticated investors who participated to the Placement following receipt of shareholder approval.
- 150 million quoted Options exercisable at $0.012 (1.2 cents) each and expiring on 10 May 2026 were also issued on 22 November 2023 ("Broker Options"). The purpose of the issue of Broker Options to the Joint Lead Managers was for fees payable to them as joint lead managers for services.

The Company also had 122,443,182 quoted Options exercisable at $0.035 each which expired on 31 December 2023 without being exercised.

In addition, during the quarter the Company invested ~A$878K in R&D activities and incurred administration and corporate costs of ~A$660K. Administration and corporate costs during the quarter were higher compared to historical amounts due to investor relationships, capital raising fees and insurance renewals. At the end of the quarter, the Company held ~A$5.5 million in cash.

Payments to related parties and their associates during the quarter, as outlined in Section 6 of the accompanying Appendix 4C to these quarterly activities report, were ~A$53K.

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 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 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 forwardlooking 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 December 2023

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (9 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	23	758
1.2	Payments for		
	(a) research and development	(878)	(2,313)
	(b) product manufacturing and operating costs	(92)	(212)
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs*	3	(552)
	(f) administration and corporate costs	(660)	(1,568)
	(g) patent portfolio costs	(75)	(295)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	24	36
1.5	Interest and other costs of finance paid	(3)	(12)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	37	724
1.8	Other (EMDG)	-	-
1.9	**Net cash from / (used in) operating activities**	**(1,621)**	**(3,434)**

**A percentage of staff costs are reallocated to payments for research and development. Amounts during the current quarter was adjusted to reflect the staff cost reallocation to payments for research and development during 1 July to 31 December 2023.*

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 (9 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)	2,644	8,004
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	(237)	(463)
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(a)	Other – Payment of principal element of lease liabilities	(19)	(71)
3.9(b)	Other – Advances for shares*	-	-
3.10	**Net cash from / (used in) financing activities**	**2,388**	**7,470**

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 months) $A'000
4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	4,737	1,468
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,621)	(3,434)
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)	2,388	7,470
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**5,504**	**5,504**

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	5,488	4,221
5.2	Call deposits	16	516
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)**	**5,504**	**4,737**

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	(53)
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)	(1,621)
8.2	Cash and cash equivalents at quarter end (item 4.6)	5,504
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	5,504
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	**3.39**

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: N/A

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: N/A

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: N/A

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: 31 January 2024

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.