



ASX Announcement

30 April 2024

Avecho Quarterly Activities Report and Appendix 4C

Melbourne, Australia, 30 April 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 March 2024.

During the quarter, the Company marked a major milestone, with the commencement of its pivotal Phase III trial of its proprietary CBD soft gel capsule targeting insomnia. Further details on the structure of the study are outlined below.

PHASE III STUDY COMMENCES FOLLOWING FINAL ETHICS APPROVAL

In March 2024, the Company commenced patient recruitment for its Phase III clinical trial testing its oral cannabidiol TPM®-enhanced soft-gel capsule for insomnia, the largest insomnia study of its kind testing cannabidiol.

The trial is seeking to recruit 519 patients across sites located in Melbourne, Sydney, Central Coast, Brisbane, and Perth. The treatment groups will compare nightly cannabidiol doses of 75 and 150mg cannabidiol with placebo over an 8-week dosing period.

The trial has been designed to meet the requirements of key global regulatory agencies, including Australia's key regulatory body, the Therapeutics Goods Administration ("TGA"). The Company met with the TGA during the quarter to present the final Phase III insomnia clinical trial design and planned submission strategy. The TGA has not recommended any changes to the trial design and submission strategy and the program has commenced as planned. Although non-binding and given without prejudice the positive response from the TGA reinforces Avecho's confidence that the trial, if successful, may support an Australian regulatory approval.

Australia's unique regulatory environment provides an outstanding commercial opportunity to Avecho. During 2020, the TGA announced it would allow cannabidiol products to be sold over the counter in Australia subject to appropriate regulatory approvals, therefore incentivising pharmaceutical development and a shift away from unregistered cannabinoid products. To date, no Phase III cannabidiol trials in Australia have succeeded. Avecho is targeting to be the first company to gain such approval with its oral CBD TPM soft-gel capsule for the treatment of insomnia.

Avecho's trial will recruit eligible participants who are 18 years or older; who have had difficulty getting to sleep, staying asleep and/or waking up earlier in the morning than desired, for at least the past three months (or are diagnosed with insomnia); and/or have a regular time period spent in bed, either sleeping or trying to sleep.

The commencement of the trial follow Avecho receiving final ethics approval after it submitted amendments to the study in December 2023.

The ethics approval included measures to streamline and enhance efficiency within the trial, reinforcing the planned study design, further separating the methodology away from that employed in unsuccessful Phase III trials for CBD in the treatment of insomnia in Australia to date. It also allows Avecho to more efficiently deploy funds made available to the Company following its capital raising in 2023.

The commencement of the study produced wide ranging media interest with segments broadcast nationally on Channel 9 (<https://www.youtube.com/watch?v=s6GCPzJ92Rc>), [Channel 7](https://twitter.com/7NewsMelbourne/status/1773228526193492070) (<https://twitter.com/7NewsMelbourne/status/1773228526193492070>) and a variety of radio networks.

The Company will update the market as recruitment continues.

CORPORATE

During the quarter ended 31 March 2024, the Company invested ~A\$406K in R&D activities and incurred employment, administration and corporate costs of ~A\$376K. At the end of the quarter, the Company held ~A\$4.6 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 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

32 056 482 403

Quarter ended ("current quarter")

31 March 2024

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	1
1.2 Payments for		
(a) research and development	(406)	(406)
(b) product manufacturing and operating costs	(70)	(70)
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs*	(140)	(140)
(f) administration and corporate costs	(236)	(236)
(g) patent portfolio costs	(40)	(40)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	14	14
1.5 Interest and other costs of finance paid	(2)	(2)
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	(879)	(879)

*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	-	-
(l) intellectual property	-	-

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
(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(a) Other – Payment of principal element of lease liabilities	(19)	(19)
3.9(b) Others	-	-
3.10 Net cash from / (used in) financing activities	(19)	(19)

4. Net increase / (decrease) in cash and cash equivalents for the period		
4.1 Cash and cash equivalents at beginning of period	5,504	5,504
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(879)	(879)

Appendix 4C
Quarterly cash flow report for entities subject to Listing Rule 4.7B

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)	(19)	(19)
4.5	Effect of movement in exchange rates on cash held	1	1
4.6	Cash and cash equivalents at end of period	4,607	4,607

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	4,591	5,488
5.2	Call deposits	16	16
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)	4,607	5,504

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.

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

7. Financing facilities	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
<i>Note: the term "facility" includes all forms of financing arrangements available to the entity.</i>		
<i>Add notes as necessary for an understanding of the sources of finance available to the entity.</i>		
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)	(879)
8.2 Cash and cash equivalents at quarter end (item 4.6)	4,607
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	4,607
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	5.24
<i>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.</i>	
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	
<i>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.</i>	

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: 30 April 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.