ASX Announcement

31 January 2023

Avecho Quarterly Activities Report and Appendix 4C

Key Highlights

- Ethics approval received for Phase III clinical trial of oral CBD softgel capsule targeting insomnia
- Agreement signed with NYSE-listed consumer products leader Perrigo to develop TPM®-enhanced ibuprofen gel
- Avecho's TPM®-enhanced Vitamin K injectable product presented to the FDA by Athenex as part of pre-IND meeting request

Melbourne, **Australia, 31 January 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 December 2023.

Avecho CEO Dr Paul Gavin commented: "*Throughout our updates during calendar 2022 we've reinforced that business development efforts have been a focus for management, and the announcements we've recently delivered, including the development agreement with Perrigo and potential license for our Vitamin K technology with Athenex, are the result of this work throughout the year. As we enter 2023, we're looking forward to further these and potential additional agreements, as well as embarking on the Phase III clinical trial of our oral CBD softgel capsule for which we recently received ethics approval.*"

Ethics approval received for Phase III trial of CBD soft-gel capsule

During December the Company was pleased to receive formal ethics approval for the pivotal Phase III clinical trial testing its oral CBD softgel capsule for insomnia.

The study will be the largest randomised, placebo-controlled study being undertaken in Australia to support registration of cannabidiol (CBD) as an over-the-counter medicine with the Therapeutic Goods Administration (TGA). The clinical trial has been designed to produce clinical evidence which is applicable to support product registration with the key global regulatory bodies including the TGA, FDA and EMEA.

The study will be a multicenter study conducted at up to 10 sites around Australia. The lead site will be Monash Medical Centre in Melbourne, under the supervision of Principal Investigator, Associate Professor Darren Mansfield, Deputy Director of Monash Health.

The study will enrol 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. It will have two primary endpoints:

- To investigate the effect of the administration of 75 mg and 150 mg per day CBD TPM® capsules versus placebo on reductions in insomnia severity after 8 weeks of treatment, as measured by the Insomnia Severity Index (ISI), and;
- To investigate the effect of the administration of 75 mg and 150 mg per day CBD TPM® capsules versus placebo on reductions in insomnia severity after 8 weeks of treatment, as measured by subjective sleep efficiency.

Key secondary endpoints will examine specific aspects of sleep, including time to fall asleep (sleep onset latency; SOL), the time spent waking up after sleep is initiated (wake after sleep onset; WASO) and further secondary endpoints related to other aspects of sleep and also anxiety. Further exploratory endpoints have been included to identify future indications that may benefit from the specific combination of TPM® and CBD.

Avecho has already established the single dose absorption profile from its softgel capsule, but blood will be collected across the 8-week study period to establish the steady state CBD concentrations after longer periods of dosing.

The study will incorporate an interim analysis after roughly 300 patients have been dosed to conduct a powering and futility assessment. The powering calculation will be used to confirm the number of patients required to complete the study. The futility assessment will be used to determine whether there is any effect present in the study, or whether it should be terminated early.

Avecho will inform the market as to the commencement and any updates regarding the trial.

Development agreement with leading US consumer healthcare company Perrigo

Also in December, 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.

Perrigo was drawn to compelling evidence that TPM® may improve the performance of ibuprofen gels. Development work conducted by Avecho has shown that ibuprofen gels formulated with TPM® can increase the transdermal absorption of ibuprofen by ~200% when compared with commercially available topical ibuprofen products such as Nurofen, Fenbid, and Ibuleve.

Perrigo's major brands include Herron, Nicotinell and OsteoEze, with its global portfolio of self-care products generating net sales of more than US$4 billion in 2021.

Avecho's Vitamin K injection presented to FDA in partnership with Athenex

Post quarter end, the Company was pleased to announce 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.

Pending favourable feedback from the FDA, Athenex will sign a license and development agreement with Avecho for the Vitamin K product and complete the remaining development work and registration for US commercialization. The final commercial terms of a subsequent agreement will be determined once FDA feedback is received.

Phytonadione (Vitamin K1) injections are used to treat bleeding or clotting problems caused by Vitamin K deficiency, reactions to certain medications, or other medical conditions that lead to thinning of the blood. It is routinely administered to infants at birth as a prophylactic, providing protection against bleeding, and in 2021 the US had an overall adult and pediatric approximate market size of $87M USD, with over 4.9M units sold.

Athenex's Pharmaceutical Division (APD) operates its specialty pharmaceuticals business, sourcing injectable and oral products for the US market through license and development agreements with a network of global partners.

Corporate

During the Quarter ended 31 December 2022, Avecho had net operating outflow of $763K, including $696K invested in R&D activities. Administration and corporate costs were $428K during the quarter.

Avecho continues to manufacture and sell Vital ET® to Ashland for use in the global personal care industry, receiving $425K from sales made during the current and previous quarter.

At the end of the quarter, the Company held $1,468K 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 $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 (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 December 2022

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (12 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	425	1,193
1.2	Payments for		
	(a) research and development	(696)	(1,476)
	(b) product manufacturing and operating costs	(49)	(557)
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs*	21	(653)
	(f) administration and corporate costs	(428)	(999)
	(g) patent portfolio costs	(48)	(214)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	-	4
1.5	Interest and other costs of finance paid	-	(2)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	(45)	963
1.8	Other (EMDG)	57	77
1.9	**Net cash from / (used in) operating activities**	**(763)**	**(1,664)**

**A percentage of staff costs are reallocated to payments for research and development. Current quarter and year-to-date payments for staff costs are adjusted for the additional research and development activities during the Q3 2022 and Q4 2022.*

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(h) entities	-	-
	(i) businesses	-	-
	(j) property, plant and equipment	-	(53)
	(k) investments	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 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**	**-**	**(53)**

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	(20)	(80)
3.10	**Net cash from / (used in) financing activities**	**(20)**	**(80)**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	2,251	3,265
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(763)	(1,664)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	(53)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(20)	(80)
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**1,468**	**1,468**

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	1,382	2,165
5.2	Call deposits	86	86
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)**	**1,468**	**2,251**

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)	(763)
8.2	Cash and cash equivalents at quarter end (item 4.6)	1,468
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	1,468
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	**1.93**

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 Q4 spend included annual insurance premiums to cover the Company for the next twelve (12 months). These insurance premiums significantly increased the administration expenses during Q4 but will not be incurred again until Q4 2023.

The Company also reported increased research and development expenses during Q4. These expenses include advanced preparatory clinical activities to support the Company's future Phase III clinical trial.

The Company will receive its R&D tax return in the coming months which will further reduce the Company's level of negative operating cash flow below that experienced in Q4.

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: As noted in 8.6.1, operating expenses are expected to be lower in early 2023 than the previous quarter. The Directors continue to review the Company's costs and expenses and assess potential sources of revenues and funding including application for research and development incentive application for 2022. The Company's current cash balances are expected to be sufficient to cover the operating expenses in the near future. However, the Company has a successful history of capital raising and if required the Company will raise additional capital by one of or a combination of the following: placement of shares, rights issue, share purchase plan. In addition, the Company also have following funding options

- Potential debt financing of the R&D tax incentive so the Group can receive the money in advance; and
- Defer certain R&D expenditure to the future to reduce the cash outflows.

The Directors will continue to monitor the ongoing funding requirements of the Company.

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: 31 January 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.