ASX Announcement

31 January 2022

ASX Market Announcements
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Melbourne VIC 3000

Avecho Quarterly Activities Report and Appendix 4C

Melbourne, **Australia, 31 January 2022** - Avecho Biotechnology Limited (ASX: AVE) ("Avecho" or the "Company"), committed to developing and commercialising innovative Human and Animal Health products using its proprietary TPM® drug delivery system, is pleased to release its Quarterly Activities Report and Appendix 4C for the quarter ended 31 December 2021.

Key Highlights

- Completion of Phase I Clinical trial characterising the absorption profile of cannabidiol from the Company's CBD soft-gel product
- First licensing deal for the CBD soft-gel capsule with Medterra Pharma, for US clinical development targeting an arthritis indication
- Collaboration with the Lambert Initiative to conduct a Phase IIa clinical trial examining whether CBD can provide relief from symptoms of osteoarthritis after topical application
- Cash balance of $3.265m on 31 December 2021

Operations

Avecho Biotechnology completed a major milestone in the development of its proprietary cannabidiol ("CBD") soft-gel capsule during Q4 2021, with the completion of its Phase I clinical trial (the "Study").

The Study was designed to characterise the single dose pharmacokinetics ("PK") of cannabidiol absorbed from a single 75 mg and 150 mg oral dose of its CBD soft-gel products. This information is required for future product registration with the TGA or FDA. The 75 mg and 150 mg doses align with the TGA's down-scheduling of CBD, which has specified that future over-the-counter CBD products must have a maximum daily dose of 150 mg.

The Study was conducted at CMAX in Adelaide with 16 healthy volunteers. Subjects received both doses over a period of two weeks, with each dose preceded by an overnight fast. Blood samples were collected for 48 hours after each dose and assayed for CBD content. All 16 subjects completed both treatment periods.

The CBD absorption profile and PK parameters of both the 75 mg and 150 mg doses were well characterised. There was a linear relationship between doses with the average amount of drug absorbed from the 150 mg dose being approximately double that of the 75 mg dose. The two doses exhibit minor differences in delivery profile, with mean peak plasma concentrations for the 75 mg dose appearing two hours after dosing, whereas peak plasma concentrations for the 150 mg dose were evident three hours after dosing. The absorption period of the 150 mg dose was also longer, with CBD detected in the blood one week after dosing.

Both doses of the CBD soft-gel were well tolerated, with all adverse events characterised as mild and no adverse events of concern were related to the Study medication.

The Study is a key value driver for the Company, informing the design of Avecho's subsequent clinical development program and forming a crucial piece of a future regulatory submission. The Company has submitted a range of questions to the TGA regarding next steps in the further clinical development and registration of the product for a sleep related indication, and is expecting a response in Q1 CY2022.

While Avecho has focused on a sleep related indication, the Company aims to derive maximum value from its CBD soft-gel product by collaborating with reputable partners to progress it toward regulatory approval in a number of parallel indications. In December 2021, the Company entered into its first license and supply agreement for its CBD soft-gel product with Medterra Pharma. Medterra is one of the most successful CBD companies in the United States, known for developing and selling science-backed products in the consumer space. Its business development activities are now shifting to emerging opportunities in the pharmaceutical space, with the launch of Medterra Pharma.

Medterra Pharma was granted exclusive rights to develop and commercialise Avecho's soft-gel CBD capsule for the oral treatment of arthritis (excluding in Australia and New Zealand), which will commence with a randomised, double-blind, placebo controlled clinical trial exploring the therapeutic potential of the CBD soft-gel product for reducing pain in patients with osteoarthritis of the knee. The study already has Institutional Review Board approval with an Investigational New Drug Application ("IND") aiming to be submitted to the FDA Q1 2022.

Avecho is currently engaged in a number of further partnering discussions, with additional outreach planned in Q1 2022 now that Phase I trial results are available.

Avecho CEO, Dr Paul Gavin, said: *"Our team is exceptionally proud of the progress we have made in our Cannabinoid program. Our methodical collection of early phase data, announced in Q4 2021, will empower us to scale up manufacturing for our oral CBD soft-gel capsule; support a future TGA submission dossier; produce larger commercial batches; and progress the product into pivotal efficacy studies for a sleep indication too. "*

Beyond the oral CBD soft-gel capsule, Avecho continues to explore further clinical applications of its formulations in partnership with reputable, independent experts. In October 2021, the Company announced a collaboration with leading Australian research group for cannabinoid therapeutics, the Lambert Initiative ("the Lambert"), at the University of Sydney to conduct a proof of concept study to examine whether topically applied CBD can provide relief from symptoms of osteoarthritis.

The Phase IIa Study (the "PIIa Study") is being run by Principal Investigator, Dr Daniel Lewis, from the Daniel Lewis Rheumatology Centre, and Co-Investigator, Professor Iain McGregor, from the Lambert. The PIIa Study has been initiated in response to growing demand from patients who are unsatisfied with their level of pain management provided by current treatments for osteoarthritis of the hand. This study is currently scheduled to begin Q1 2022.

Avecho's partnered animal health studies commenced in Q4 2021, with results expected H1 2022. These studies are examining new applications for TPM® in feed products for weaner pigs. Positive results would be used to support a commercial deal for the inclusion of TPM® in our partner's commercial livestock products. In collaboration with this program, Avecho recently finalised a dossier for submission to the European Food Safety Authority ("EFSA"). EFSA's scientific evaluation process will conclude with a written assessment of the data pack that will formally articulate what additional studies EFSA may require to support the approval of feed products containing TPM®.

Corporate

During the quarter ended 31 December 2021, Avecho had net operating outflow of $812K, including $632K invested in R&D activities. Adminstration and corporate costs were $424K during the quarter. The Company received $344k from its R&D tax return related to FY 2020. The 2021 R&D tax return is anticipated to be over $1M, and will be submitted early in Q1 CY2022.

Avecho continues to manufacture and sell Vital ET® to Ashland for use in the global personal care industry, receiving $393K from sales made during the current and previous quarter.

At the end of the quarter, the Company held $3.265m in cash. The Company remains committed to its R&D programs, while continuing to demonstrate prudent cash management and adapt its operational policies and procedures in line with COVID-19 mitigation measures.

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 $136K. These payments are related to director fees and short term incentives paid during the the quarter.

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 2021

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	409	788
1.2	Payments for		
	(a) research and development	(632)	(1,706)
	(b) product manufacturing and operating costs	(155)	(381)
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs*	(293)	(1,005)
	(f) administration and corporate costs	(424)	(1,030)
	(g) patent portfolio costs	(61)	(246)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	1	1
1.5	Interest and other costs of finance paid	(1)	(7)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	344	516
1.8	Other (EMDG, PAYG subsidy)	-	-
1.9	**Net cash from / (used in) operating activities**	**(812)**	**(3,070)**

**Some staff costs are reallocated in payments for research and development*

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(13)	(202)
	(d) investments	-	-
	(e) intellectual property	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
	(f) 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**	**(13)**	**(202)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	5,060
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	-	(324)
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	(19)	(72)
3.10	**Net cash from / (used in) financing activities**	**(19)**	**4,664**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	4,109	1,873
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(812)	(3,070)

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)	(13)	(202)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(19)	4,664
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**3,265**	**3,265**

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	3,179	4,023
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)**	**3,265**	**4,109**

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	136
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)	(812)
8.2	Cash and cash equivalents at quarter end (item 4.6)	3,265
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	3,265
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	**4.02**

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 2022

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.