



## ASX Announcement

28 April 2021

ASX Market Announcements  
ASX Limited  
Level 4  
North Tower, Rialto  
525 Collins Street  
Melbourne VIC 3000

# Avecho Quarterly Activities Report and Appendix 4C

**Melbourne, Australia, 28 April 2021** - Avecho Biotechnology Limited (ASX: AVE) ("Avecho" or the "Company"), a company that develops and commercialises innovative Human and Animal Health products using its proprietary drug delivery system called TPM<sup>®</sup>, is pleased to release its Quarterly Activities Report and Appendix 4C for the quarter ended 31 March 2021.

### Key Highlights

- Capital Raise (\$5.06M) to fund ongoing development of pharmaceutical CBD product.
- Development of Avecho's enhanced oral CBD product continued;
  - Recruitment on the CACOS observational clinical trial continued – 41 patients enrolled by end of March.
  - Phase I trial design completed and submitted to ethics; ethics approval received in April
  - CBD product for use in Phase I-III trials began manufacturing development as a softgel capsule by Catalent
  - Strategic workshops held with Cannvalate to define development path toward TGA registration
- Business Development campaign continues, with ongoing discussions related to assets in both the human and animal health portfolio.
- Cash balance at the close of quarter was \$5.7m.

### Capital Raise

Avecho conducted a \$5.06M raise at the beginning of February to fund the continued development and registration of a new pharmaceutical cannabidiol (CBD) product. The Placement was cornerstoned by \$1m from Horizon 3 Biotech. Peak Asset Management, Lead Manager for the Placement, underwrote the remaining \$4m of the \$5m to be raised. The company issued 230m fully paid ordinary shares at an issue price of \$0.022 per share to raise proceeds of \$5.06m. Each New Share had attaching Listed Options on a 1:2 basis, exercisable at \$0.035 each, expiring 31 December 2023. The Placement Price represented a 9.67% discount to the five-day volume weighted average price (VWAP) on the ASX of \$0.02432 per share up to 4 February 2021. Peak Asset received over \$23m bids by close of business on 9 February 2021, signalling strong support.

### Operations

The continued development of Avecho's pharmaceutical CBD product was the main focus of Q1 2021. Having demonstrated significant increases in oral bioavailability from CBD formulations in an animal model during 2020, the company focused on advancing the product through clinical trials and defining the development plan required for eventual product registration with the TGA.

Avecho joined Australia's largest running observational study of medicinal cannabis products, the CA clinics Observational Study (CACOS) at the end of December 2020. This study will test the performance of its enhanced oral CBD formulation in human patients being prescribed medicinal cannabis for a range of indications. Performance will be compared against commonly prescribed CBD formulations. Recruitment for the study began late December, and will continue on an ongoing basis throughout 2021 to maximize the



number of patients dosed with both the CBD TPM<sup>®</sup> and commercial comparator formulations. By the end of March 2021, 41 patients had been recruited onto the study. These patients are distributed across a range of indications, including various pain conditions, anxiety and sleep disorders. As meaningful numbers of active patients accumulate for any single indication, the company will begin data analysis of the effect size produced by comparative doses of the enhanced formulation.

Avecho continued to build the development plan to take an enhanced CBD softgel toward TGA registration. The protocol for a Phase I pharmacokinetic study designed to characterise the drug absorption from the Avecho CBD formulation was completed and submitted for ethics approval. The study will measure the safety and absorption profile of the CBD product developed with TPM<sup>®</sup> and the data will form an integral part of a future TGA submission and drug label. The study will take place at CMAX in Adelaide with 16 healthy volunteers. The study will be a cross-over design comparing the absorption of CBD after consumption of soft-gel capsules at two different doses; 75 mg and 150 mg. These clinical doses were chosen to 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 75 mg CBD dose per soft-gel capsule will support twice daily dosing for indications benefiting from prolonged drug delivery (such as anxiety), or for the consumption of two capsules together for indications requiring a higher, single dose (for indications such as insomnia).

In parallel with the clinical trial work, Avecho has begun the chemistry, manufacturing and control (CMC) work required to prove a pharmaceutical product can be reproducibly manufactured to pharmaceutical standards with acceptable stability. CMC is an integral component of a product application to the TGA or FDA. Catalent is currently supporting the development of the CBD soft-gel capsules for use in the clinical trial at its St. Petersburg, Florida, facility in the U.S. based on Avecho's prototype formulation. Catalent is a leading global provider of advanced drug delivery technologies, development, and manufacturing solutions to help life science innovators develop and launch successful pharmaceuticals.

Avecho began planning the larger development program beyond this Phase I study, with a target of registering the product with the TGA. This path forward is being developed with a number of subject matter experts, including the Medicinal Cannabis Research Collaboration (MCRC), a joint venture between Cannvalate and a major Melbourne university. This work is ongoing, and aims to determine the most appropriate indication and design for a pivotal Phase III clinical trial that would support product registration. The Company will request a TGA presubmission meeting to validate its plans once they are finalised.

Independent of Avecho's cannabinoid program, external licensing discussions for the non-cannabinoid programs continued throughout Q1. Licensing opportunities for a number of Avecho's portfolio products are still under review by third parties in both the pharmaceutical and animal health spaces, and involve a range of territories. As mentioned previously, whilst the Company would like to conclude these discussions as rapidly as possible, the timeframe for decision making is ultimately in the hands of the potential licensees and their commercial assessments.

### **Corporate**

During February 2021, Avecho raised \$5.06m (before transaction costs of \$324K) by issuing 230m fully paid ordinary shares at an issue price of \$0.022 via placement. In addition, during the quarter, Avecho had net operating outflow of \$847K, including \$338K invested in R&D activities. At the end of the quarter, the Company held \$5.7m 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 6.1 of the accompanying Appendix 4C to this quarterly activities report were \$63K. These payments are related to director fees for 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](http://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 2021

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (3 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	20	20
1.2 Payments for		
(a) research and development	(338)	(338)
(b) product manufacturing and operating costs	(63)	(63)
(c) advertising and marketing	-	-
(d) leased assets	(17)	(17)
(e) staff costs*	(151)	(151)
(f) administration and corporate costs	(217)	(217)
(g) patent portfolio costs	(81)	(81)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	-	-
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, PAYG subsidy)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(847)</b>	<b>(847)</b>

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

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

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

<b>3. Cash flows from financing activities</b>		
<b>3.1 Proceeds from issues of equity securities (excluding convertible debt securities)</b>	<b>5,060</b>	<b>5,060</b>
<b>3.2 Proceeds from issue of convertible debt securities</b>	-	-
<b>3.3 Proceeds from exercise of options</b>	-	-
<b>3.4 Transaction costs related to issues of equity securities or convertible debt securities</b>	<b>(324)</b>	<b>(324)</b>
<b>3.5 Proceeds from borrowings</b>	-	-
<b>3.6 Repayment of borrowings</b>	-	-
<b>3.7 Transaction costs related to loans and borrowings</b>	-	-
<b>3.8 Dividends paid</b>	-	-
<b>3.9 Other - Payment of principal element of lease liabilities</b>	<b>(19)</b>	<b>(19)</b>
<b>3.10 Net cash from / (used in) financing activities</b>	<b>4,717</b>	<b>4,717</b>

<b>4. Net increase / (decrease) in cash and cash equivalents for the period</b>		
<b>4.1 Cash and cash equivalents at beginning of period</b>	<b>1,873</b>	<b>1,873</b>
<b>4.2 Net cash from / (used in) operating activities (item 1.9 above)</b>	<b>(847)</b>	<b>(847)</b>

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (3 months) \$A'000</b>
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)	4,717	4,717
4.5	Effect of movement in exchange rates on cash held	2	2
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>5,745</b>	<b>5,745</b>

<b>5.</b>	<b>Reconciliation of cash and cash equivalents</b> at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	<b>Current quarter \$A'000</b>	<b>Previous quarter \$A'000</b>
5.1	Bank balances	5,659	1,787
5.2	Call deposits	86	86
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>5,745</b>	<b>1,873</b>

<b>6.</b>	<b>Payments to related parties of the entity and their associates</b>	<b>Current quarter \$A'000</b>
6.1	Aggregate amount of payments to related parties and their associates included in item 1	63
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.*

<b>7. Financing facilities</b>	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
<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 <b>Total financing facilities</b>	-	-
7.5 <b>Unused financing facilities available at quarter end</b>		-
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	

<b>8. Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1 Net cash from / (used in) operating activities (item 1.9)	(847)
8.2 Cash and cash equivalents at quarter end (item 4.6)	5,745
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	5,745
8.5 <b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	<b>6.78</b>
<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: 28 April 2021  
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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.