



## ASX Announcement

29 April 2022

# Avecho Quarterly Activities Report and Appendix 4C

## Key Highlights

- Completion of Phase II Clinical Trial examining its proprietary topical cannabidiol (CBD) gel for the management of pain associated with arthritis of the hand;
- First licensing and supply agreement for the use of TPM® in the US recreational cannabis space;
- TGA feedback on Phase III CBD soft-gel program and completion of initial Phase III Clinical Trial design;
- Cash balance of \$2.44m on 31 March 2022.

**Melbourne, Australia, 29 April 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 March 2022.

Throughout the quarter, Avecho remained heavily focused on advancing its CBD soft-gel product in Q1 CY2022 whilst also pursuing large, untapped licensing opportunities in the US cannabis space.

## Topical CBD gel for Osteoarthritis: positive clinical data

At the end of March, Avecho announced results from a Phase II Clinical Trial (the "Trial") that tested a new product, a proprietary topical CBD gel, for its ability to manage painful symptoms associated with osteoarthritis ("OA") of the hand.

The Trial was run by Principal Investigator, Dr Daniel Lewis, from the Daniel Lewis Rheumatology Centre; and Co-Investigator, Professor Iain McGregor, from the Lambert Initiative, Australia's leading research group for the discovery, development, and optimisation of safe cannabinoid therapeutics.

The single-centre proof-of-concept trial investigated the effects of a topical CBD gel on symptomatic, painful OA of the hand, affecting the fingers and/or thumb. A group of 15 patients applied Avecho's proprietary TPM® formulation daily to the affected joints of a single hand. The Trial was run over a 6 week period, including 1 week of baseline measurements, 4 weeks of treatment, and a subsequent 1 week of washout after the conclusion of dosing.

Four week treatment with Avecho's proprietary topical CBD formulation resulted in highly significant improvements ( $p < .001$ ) in patient observed (i) reductions in pain, (ii) increases in grip strength, (iii) improvements in hand functionality, (iv) self-reported stiffness of the fingers and (v) self-reported anxiety.

**Avecho CEO, Dr Paul Gavin, said:** *"Given this initial study was relatively small, we were very encouraged by the results produced by topical application of our CBD gel. In addition to the improvements in pain, grip strength and hand function, many subjects reported resuming leisure activities that had previously proven difficult due to their poor hand function."*

Avecho will now plan larger placebo-controlled studies in collaboration with the Lambert Initiative. Results of the current Trial will also be presented by the Lambert Initiative at the 32<sup>nd</sup> Annual International Cannabinoid Research Society Symposium ("ICRS") in Galway, Ireland, in June 2022. The ICRS conference is the premier annual meeting for cannabinoid research.



## **Commercialising the CBD program: valuable partnerships**

Avecho has now added its topical CBD product to ongoing commercial discussions related to the application of TPM® to CBD products across a range of dosage forms.

In December 2021, the Company entered into its first license and supply agreement for its CBD soft-gel product with Medterra Pharma (now named Perland Pharmaceuticals) for the treatment of arthritis. Avecho has been working with Perland during Q1 to map out CBD capsule supply requirements for their planned clinical trials.

In February 2022, the Company announced its second deal in the CBD market, entering into a licensing and supply agreement with Team SAAS LLC ("SAAS") for the use of TPM® in recreational products in the US. SAAS will develop and commercialise a unique cannabis distillate that will be sold to recreational cannabis companies as a raw material for the manufacture of their own recreational cannabis products. Initial findings by SAAS in the US have demonstrated that the inclusion of TPM® in edible gummies containing cannabis may increase the onset, duration or magnitude of effect. Avecho has now completed manufacturing of the initial order of TPM® to support the SAAS product.

This Agreement signals a strategic step forward in Avecho's ambitions to increase the breadth of its cannabis products and market opportunities leveraging TPM® formulations. Avecho is currently engaged in a number of partnering discussions related to the use of TPM® in a variety of dosage forms.

**Avecho CEO, Dr Paul Gavin, said:** *"The data we have generated across our expanded cannabinoid program is beginning to pay dividends. Our deep biotechnology expertise and experience in non-cannabinoid drug development is seen as a major differentiator to medicinal cannabis companies for potential licensees. We are focused on expanding our business development activities with the aim of closing further deals in the various cannabinoid markets."*

## **CBD soft-gel capsule: a key focus**

While progress for Avecho's topical CBD gel and licensing fronts have been important, the Company's focus remains on the development of the CBD soft-gel capsule for over-the-counter registration with the TGA for an insomnia-related indication. During Q1, Avecho finally received TGA feedback on questions related to the Phase III program and associated supporting information. The Company subsequently convened a panel of local and international sleep experts to revise the study design for the proposed Phase III Clinical Trial. While TGA registration is the initial focus, the Company is adamant the study should be applicable to international regulatory agencies (FDA, EMA). Consequently, design aspects related to the testing regime, the primary/secondary endpoints and patient inclusion/exclusion criteria become critical. In collaboration with its team of associated sleep and regulatory experts, Avecho has now completed the initial study design and is currently engaging the required clinical service providers to drive the study. The Phase III Clinical Trial will be the focus of 2022 and will kick off later this year.

## **Corporate**

During the quarter ended 31 March 2022, Avecho had net operating outflow of \$757K, including \$286K invested in R&D activities. Administration, employment and patent portfolio costs were \$522K in total during the quarter. The 2021 R&D tax return was submitted during the quarter and is anticipated a refund of \$1.02M.

At the end of the quarter, the Company held \$2.44M in cash. In addition, the Company had \$0.4M trade receivable from customers. 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 \$53K. These payments are related to director fees 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](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 2022

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	360	360
1.2 Payments for		
(a) research and development	(286)	(286)
(b) product manufacturing and operating costs	(329)	(329)
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs*	(271)	(271)
(f) administration and corporate costs	(178)	(178)
(g) patent portfolio costs	(73)	(73)
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)	20	20
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(757)</b>	<b>(757)</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:		
(h) entities	-	-
(i) businesses	-	-
(j) property, plant and equipment	(48)	(48)
(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)	-	-
<b>2.6 Net cash from / (used in) investing activities</b>	<b>(48)</b>	<b>(48)</b>

<b>3. Cash flows from financing activities</b>		
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)	(20)
<b>3.10 Net cash from / (used in) financing activities</b>	<b>(20)</b>	<b>(20)</b>

<b>4. Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1 Cash and cash equivalents at beginning of period	3,265	3,265
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(757)	(757)

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

<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)	(48)	(48)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(20)	(20)
4.5	Effect of movement in exchange rates on cash held	-	-
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>2,440</b>	<b>2,440</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	2,354	3,179
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>2,440</b>	<b>3,265</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	(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

<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. 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)	(757)
8.2 Cash and cash equivalents at quarter end (item 4.6)	2,440
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	2,440
8.5 <b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	<b>3.22</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: 29 April 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.