ASX Announcement

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ASX Market Announcements
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Avecho Quarterly Activities Report and Appendix 4C

Melbourne, **Australia, 27 July 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®, is pleased to release its Quarterly Activities Report and Appendix 4C for the quarter ended 30 June 2021.

Key Highlights

- Development of Avecho's enhanced oral CBD product continued;
  - CBD soft-gel capsule design finalised by Catalent.
  - TGA meeting activities planned with Cannvalate to gain feedback on CBD program.
  - Recruitment on the CACOS observational clinical trial continued – 130 patients enrolled by end of June.
- AB Vista developing TPM formulations to control post-weaning diarrhea in pigs.
- Cash balance at the close of quarter was $4.8m.

Operations

The continued development of Avecho's pharmaceutical CBD soft-gel product was the main focus during Q2 2021. During this period, the program priority was the finalisation of the CBD soft-gel product, and the supporting chemistry, manufacturing and control (CMC) work. CMC is an integral component of a product application to the Therapeutic Goods Administration (TGA) or FDA for a pharmaceutical product and describes the work required to prove that it can be reproducibly manufactured to pharmaceutical standards with acceptable stability.

Avecho's leading prototype CBD oil formulation was adapted and refined to a soft-gel capsule by Catalent, a leading global provider of advanced drug delivery technologies, development, and manufacturing solutions. The refinements were designed to ensure the formulations are appropriate for inclusion in commercial capsule manufacturing lines, are compatible with candidate gelatin capsules, and most importantly, have appropriate physical and chemical stability. Commercially appropriate stability is critical given the Company's intention to register the finished product with the TGA. The formulation development work was completed in May, at a dose of 75 mg of CBD per soft-gel capsule.

Having finalized the product composition, the manufacturing campaign to produce GMP product for use in the Company's current clinical trial program began. An initial pilot batch of CBD soft-gels was successfully manufactured in May. This batch was used to validate the manufacturing process and analytical methods, as well as to inform the finished product specifications. Successful characterization of the prototype batch will allow formal GMP manufacture of the CBD soft-gel which will be used for formal stability and the planned human clinical trial campaign. This formal GMP manufacturing campaign will begin in July to produce material for use in the Company's upcoming Phase I clinical trial.

The protocol for the Phase I pharmacokinetic study was approved in April and will measure the safety and absorption profile of the CBD soft-gel product developed with TPM®. 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 entering the clinic for dosing at the end of September. It 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).

Whilst Avecho's CBD soft-gel has the potential to treat a number of candidate indications, the Company determined that insomnia should be the basis for the initial indication. This indication, and the proposed work to support the registration of the CBD soft-gel product, will be the focus or a planned meeting with the TGA. The meeting will examine aspects of Avecho's planned development program to support product registration as a Schedule 3 (S3) pharmacist only medicine in Australia.

Avecho has engaged the services of Cannvalate for the TGA presubmission. Cannvalate has developed the Medicinal Cannabis Research Collaboration as a premier Contract Research Organisation specialising in the clinical development of medicinal cannabis products. Cannvalate has already participated in TGA meetings for other medicinal cannabis companies, and is uniquely placed to help Avecho gain maximum value from the TGA interaction.

Dosing continued throughout Q2 for patients enrolled in the CA clinics Observational Study (CACOS). 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. By the end of June 2021, 130 patients had been enrolled into 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.

In June, Avecho presented at a dedicated medicinal cannabis conference for the first time. The Global Cannabis Intelligence (GCI) Summit 2021 brought together 1500+ global leaders and decision makers from across the cannabis and psychedelics sector, with a common goal to improve learning, development and advocacy in this space. The Company presented data relating to the the ability of TPM to increase both the oral and topical absorption of cannabinoids, and allowed networking with a range of new companies within the cannabinoid space.

Independent of Avecho's cannabinoid program, external licensing discussions for the non-cannabinoid programs continued thoughout Q2. In May, Avecho announced that one of its potential partners in the animal health space, AB Vista, were expanding their assessment of the utility of TPM® in livestock feeds beyond its original program analysing feed efficiency and weight gain. AB Vista are now planning to examine the application of TPM® in feed products being developed to control post-weaning diarrhoea in pigs, and pending a positive outcome of the planned programme they are undertaking, will look to partner with Avecho to bring TPM® to the animal feed market. Licensing opportunies for a number of Avecho's human health products are still under review by third parties in the pharmaceutical space, 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

The Company held its annual general meeting (AGM) on 31 May 2021, with shareholders approving all the resolutions tabled at the AGM.

During the quarter, Avecho had net operating outflow of $917K, including $352K invested in R&D activities. Adminstration and corporate costs amounted to $232K during the quarter, largely driven by recurring corporate expenses. Furthermore, Avecho has continued to manufacture and sell Vital ET® to Ashland during the transfer of manufacturing to their US facility. At the end of the quarter, the Company held $4.8m 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 $85K. 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

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	30 JUNE 2021

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (6 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	30	50
1.2	Payments for		
	(a) research and development	(352)	(690)
	(b) product manufacturing and operating costs	(37)	(100)
	(c) advertising and marketing	-	-
	(d) leased assets*	-	-
	(e) staff costs**	(282)	(433)
	(f) administration and corporate costs	(232)	(466)
	(g) patent portfolio costs	(40)	(121)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	-	-
1.5	Interest and other costs of finance paid	(4)	(4)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other (EMDG, PAYG subsidy)	-	-
1.9	**Net cash from / (used in) operating activities**	**(917)**	**(1,764)**

** Certain indirect lease related expenses were classified as payments for lease assets in the previous quarterly report. These payments are retrospectively adjusted and classified as administration and corporate costs, consistent with accounting policies of the Group.*

***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	(57)	(57)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
	(d) investments	-	-
	(e) intellectual property	-	-
	(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**	**(57)**	**(57)**

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	(16)	(35)
3.10	**Net cash from / (used in) financing activities**	**(16)**	**4,701**

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	5,745	1,873
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(917)	(1,764)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(57)	(57)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(16)	4,701
4.5	Effect of movement in exchange rates on cash held	(1)	1
4.6	**Cash and cash equivalents at end of period**	**4,754**	**4,754**

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	4,668	5,659
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)**	**4,754**	**5,745**

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	85
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)	(917)
8.2	Cash and cash equivalents at quarter end (item 4.6)	4,754
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	4,754
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	**5.18**

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: 27 July 2021

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.