



ASX Announcement

29 October 2021

ASX Market Announcements
ASX Limited
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Melbourne VIC 3000

Avecho Quarterly Activities Report and Appendix 4C

Melbourne, Australia, 29 October 2021 - 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 30 September 2021.

Key Highlights

- Enhanced CBD soft-gel capsule ready for Phase I clinical trials to characterise drug absorption
- Proposed Phase III program to be discussed with the TGA
- Commercial discussions commence on cannabinoid opportunities
- Cash balance of \$4.1M on 30 September 2021.

Operations

Avecho Biotechnology has continued to meet incremental milestones for the ongoing development of its enhanced CBD soft-gel product in Q3 CY2021. The Company has been focused on testing the CBD soft-gel product performance in a Phase I clinical trial, and Q3 saw the completion of all work required to allow dosing of human subjects in early October.

The GMP manufacturing campaign to produce clinical supply commenced in July at Catalent, USA. Final method validations were completed and all documentation and product specifications finalised to support the production and release of clinical product. The GMP clinical batch was manufactured successfully and met all specifications. CBD soft-gels were shipped to Australia for use in the Phase I PK study and also included in ongoing stability studies monitoring the chemical and physical stability of the product. Earlier batches of the CBD soft-gel capsule continue to exhibit good stability.

In parallel, the Company's Phase I study documentation was finalised to allow the formal recruitment of subjects. In September 2021, Avecho announced that recruitment of 16 healthy volunteers had begun at CMAX in Adelaide with the intent to administer a first dose in early October. The study was designed as a single dose cross-over comparing the absorption of CBD after consumption of soft-gel capsules at two different doses; 75 mg and 150 mg. Blood samples will be analysed for CBD, TP, T2P and tocopherol (the components of Avecho's TPM[®] formulation) and the results used to investigate a range of standard pharmacokinetic variables.

Dosing was successfully completed early October without any adverse effects of concern, with results expected December 2021. The Study is a key value driver for the company, forming a crucial piece of a future regulatory submission, as well as informing the design of subsequent clinical efficacy studies in an insomnia related indication. An analysis of the regulatory requirements for an insomnia related product was conducted by Cannvalate during Q3. This work has been used to refine the clinical development plans as well as identify the most important questions that require answers from the TGA. Feedback from the TGA is expected during Q4 and will be used to finalise the subsequent clinical efficacy program.



Dosing continued throughout Q3 for patients enrolled in the CA clinic's Observational Study (CACOS), with over 250 patients now dosed across the two treatment arms. Patients dosed with Avecho's CBD formulation on the CACOS study will be included as supporting information in the safety module of a future regulatory submission. Having already committed to the insomnia indication, Avecho's continued involvement on the CACOS study will now focus on accumulating a maximal number of patients to help support safety, rather than demonstrating efficacy.

The cannabinoid program has now been included in ongoing licensing discussions. During Q3, Avecho engaged further business development activities to progress licensing discussions related to its non-cannabinoid products. While this work continued, the imminent results for Avecho's Phase I PK study drove external interest in Avecho's CBD soft-gel product, both locally for the Australian market, and overseas. The Company is currently assessing a range of opportunities, with a focus on those that expand the use of the product into new indications, while allowing Avecho to focus concurrently on sleep applications.

Corporate

During the quarter ending 30 September 2021, Avecho had net operating outflow of \$495K, including \$384K invested in R&D activities. Administration and corporate costs were \$141K during the quarter. The Company received \$172K from its R&D tax return related to H2 2019. The Company's 2020 R&D tax return is due during Q4 and anticipated to be over \$300k. The 2021 R&D tax return is anticipated to be over \$1.1M, 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 \$329k of orders this quarter.

At the end of the quarter, the Company held \$4.1M 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 \$80K. 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

32 056 482 403

Quarter ended ("current quarter")

30 SEPTEMBER 2021

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (9 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	329	379
1.2 Payments for		
(a) research and development	(384)	(1074)
(b) product manufacturing and operating costs	(126)	(226)
(c) advertising and marketing	-	-
(d) leased assets*	-	-
(e) staff costs**	(279)	(712)
(f) administration and corporate costs	(141)	(607)
(g) patent portfolio costs	(64)	(185)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	-	-
1.5 Interest and other costs of finance paid	(2)	(6)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	172	172
1.8 Other (EMDG, PAYG subsidy)	-	-
1.9 Net cash from / (used in) operating activities	(495)	(2,259)

* 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	(132)	(189)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 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	(132)	(189)

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	-	(323)
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	(18)	(53)
3.10	Net cash from / (used in) financing activities	(18)	4,684

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 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	4,754	1,873
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(495)	(2,259)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(132)	(189)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(18)	4,684
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	4,109	4,109

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	4,023	4,668
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)	4,109	4,754

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	80
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
<i>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.</i>		

7.	Financing facilities <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>	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)	(495)
8.2	Cash and cash equivalents at quarter end (item 4.6)	4,109
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	3,596
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	8.30
	<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 October 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.