



## **ASX Announcement**

31 October 2023

### **Avecho Quarterly Activities Report and Appendix 4C**

**Melbourne, Australia, 31 October 2023:** Avecho Biotechnology Limited (ASX: AVE) ("Avecho" or the "Company"), focused on developing and commercialising innovative products using its proprietary Tocopheryl Phosphate Mixture ("TPM®") drug delivery system, is pleased to release its Quarterly Activities Report and Appendix 4C for the quarter ended 30 September 2023.

#### **Avecho CEO, Dr Paul Gavin, said:**

*"It was undoubtedly a key quarter for the business and investors as we concluded our capital raise. The capital we were able to secure in the Placement announced in August 2023 allows us to proceed to the Phase III clinical trial testing our oral CBD soft-gel capsule. The plans, timeline, and potential around this were discussed on our recent investor webinar, which I'd encourage all shareholders to take the time to watch."*

#### **A\$6m Placement completed to allow commencement of Phase III Clinical Trial of CBD Soft-Gel Capsule**

Avecho received firm commitments from a range of sophisticated and institutional investors to raise A\$6m by way of a Placement during the reporting period.

This comprised of:

- A first tranche of 536,128,321 fully paid ordinary shares, at an issue price of A\$0.006 per New Share to raise approximately ~A\$3.2m;
- A second tranche, conditional upon shareholder approval at a General Meeting to be held on 9 November 2023, to issue the balance of outstanding new shares at the same issue price, to raise approximately ~A\$2.8m.

Every two new shares in the Placement are accompanied by three free attaching options, exercisable at \$0.012 each, expiring on 10 May 2026.

The Placement is conducted on the same terms as Avecho's entitlement offer announced to ASX on 3 April 2023 that raised ~A\$2m from existing shareholders.

The funds raised in the Placement are to be used to advance Avecho's pivotal phase III clinical trial of the Company's proprietary TPM® enhanced cannabidiol ("CBD") soft-gel capsule to manage the symptoms of insomnia. A small proportion of the funds will be allocated to general working capital and costs of the Placement.

### **Phase III Clinical Trial Activities and Timelines**

Manufacturing activities to support the pivotal Phase III clinical trial continue at US-based Contract Manufacturing Organisation ("CMO"), Procaps Group (NASDAQ: PROC). Procaps is currently manufacturing the capsule to be used in both the pivotal Phase III clinical trial, as well as the registration batches used to demonstrate formal stability. The documentation from registration batches is a key component of a future registration submission to the TGA or FDA and proves that the product can be manufactured reproducibly with a pharmaceutically acceptable shelf life.

Further to the manufacturing, Avecho has now commenced the remaining activities required to begin the Phase III trial. These include building the electronic database that will capture all the trial information from patients, in addition to final preparations at the various sites. The trial will be conducted across 5 sites around Australia; Melbourne, Brisbane, Perth, Western Sydney and Central Coast, NSW.

The capsules for use in the Phase III trial are expected to arrive in Australia during Q4 in order to be randomized for use on study early in the new year. Patient recruitment and dosing is currently planned for January 2024. The Company anticipates it will reach its interim analysis toward September or October 2024, depending on the final rate of patient recruitment for the study.

The interim analysis will be a key milestone, allowing the company to review the data set for any observed effect, and repower the study to determine how many remaining patients are required to maximise the chance of a successful outcome. If no difference is seen between treatment groups, Avecho will not continue to dose the remaining patients.

### **Phase III Clinical Trial Investor Webinar**

Subsequent to the end of the period, Avecho's CEO Dr Paul Gavin hosted a webinar to provide more detail on the pivotal Phase III clinical trial, the accompanying activities and anticipated timelines mentioned above.

Avecho's Phase III study testing its oral CBD softgel capsule for the treatment of insomnia will be the largest of its kind to date and will compare nightly CBD doses of 75 and 150 mg CBD with placebo for their ability to improve sleep.

To view a replay of the webinar, please visit the following link:

[https://us02web.zoom.us/webinar/register/WN\\_srQ9CclRQG6ywb0JPpkEmw](https://us02web.zoom.us/webinar/register/WN_srQ9CclRQG6ywb0JPpkEmw)

### **Additional programs and partnerships**

Avecho management has continued to further activities and discussions with current and prospective partners during and subsequent to the end of the quarter. This included a business development roadshow to the US where Avecho management met with numerous pharmaceutical and recreational cannabis companies. The Company will update the market as these discussions materialise.

### **Corporate**

During the quarter ended 30 September 2023, the Company had received a sum of ~A\$3.2 million, net of transaction fees, from the afore-mentioned Placement (Tranche 1).

In addition, during the quarter the Company invested ~A\$955K in R&D activities and incurred administration and corporate costs of ~A\$360K. Administration and corporate costs during the quarter were higher compared to historical amounts due to investor relationships and capital raising fees. At the end of the quarter, the Company held ~A\$4.74 million in cash.

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 ~A\$53K.

**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 develops and commercialises innovative Human and Animal Health products using its proprietary drug delivery system called Tocopheryl Phosphate Mixture (**TPM®**). 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 and is also developing TPM® to enhance the 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")**

30 September 2023

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (9 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	25	735
1.2 Payments for		
(a) research and development	(955)	(1,435)
(b) product manufacturing and operating costs	(8)	(120)
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs*	39	(555)
(f) administration and corporate costs	(365)	(908)
(g) patent portfolio costs	(153)	(220)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	7	12
1.5 Interest and other costs of finance paid	(3)	(9)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	687
1.8 Other (EMDG)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(1,413)</b>	<b>(1,813)</b>

\*A percentage of staff costs are reallocated to payments for research and development. Amounts during the current quarter was adjusted to reflect the staff cost reallocation to payments for research and development at 30 June 2023.

<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire or for:		
(h) entities	-	-
(i) businesses	-	-
(j) property, plant and equipment	-	-
(k) investments	-	-

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (9 months) \$A'000
(l) intellectual property	-	-
(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>-</b>	<b>-</b>

<b>3. Cash flows from financing activities</b>		
3.1 Proceeds from issues of equity securities (excluding convertible debt securities)	3,217	5,163
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	(115)	(226)
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(a) Other – Payment of principal element of lease liabilities	(17)	(52)
3.9(b) Other – Advances for shares	197	197
<b>3.10 Net cash from / (used in) financing activities</b>	<b>3,282</b>	<b>5,082</b>

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (9 months) \$A'000</b>
<b>4.</b>	<b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1	Cash and cash equivalents at beginning of period	2,868	1,468
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,413)	(1,813)
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)	3,282	5,082
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>4,737</b>	<b>4,737</b>

<b>5. Reconciliation of cash and cash equivalents</b>	<b>Current quarter \$A'000</b>	<b>Previous quarter \$A'000</b>
at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts		
5.1 Bank balances	4,221	2,353
5.2 Call deposits	516	515
5.3 Bank overdrafts	-	-
5.4 Other (provide details)	-	-
<b>5.5 Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>4,737</b>	<b>2,868</b>

<b>6. 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	-
<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>	

## 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.</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)	-	-
<b>7.4 Total financing facilities</b>	<b>-</b>	<b>-</b>
<b>7.5 Unused financing facilities available at quarter end</b>		<b>-</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)	(1,413)
8.2 Cash and cash equivalents at quarter end (item 4.6)	4,737
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	4,737
<b>8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	<b>3.35</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: 31 October 2023

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.