**ASX Announcement**

25 July 2023

# Avecho Quarterly Activities Report and Appendix 4C

## Key Highlights

- Avecho concluded **AUD ~$2M Entitlement Offer** in May 2023, raised from existing shareholders, with allocation of Shortfall to occur before 10 August 2023.
- New US-based Contract Manufacturing Organisation, Procaps Group, **commenced manufacturing for cannabidiol ("CBD") soft-gel capsule** ahead of Phase III Clinical Trial for the treatment of insomnia.
- CBD soft-gel capsule successfully passed **two-year stability milestone** to meet essential pharmaceutical standards.
- US Patent and Trade Marks Office ("USPTO") allowed a **new patent application** covering an optimised manufacturing process for TPM®.
- Key **TPM business development agreements** secured with Arthur Group, for the development of cancer drugs solubilised using TPM; TPM-enhanced phytonadione (Vitamin K) on track for a Pre-Investigational New Drug Application ("IND"); and collaboration commences with the Lambert Initiative for topical and oral CBD products.
- Avecho developed first generation **TPM gummies** containing cannabinoids.

**Melbourne**, **Australia, 25 July 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 June 2023.

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

*"This has been a positive quarter for Avecho. Our long-term, carefully planned efforts to further the clinical and commercial potential of our TPM-enhanced products have gained traction. We are in the final stages of raising funds to support the commencement of our Phase III Clinical Trial for our CBD soft-gel capsule for the treatment of insomnia; we have successfully commenced manufacturing for this product; and our patent footprint is expanding in critical markets for TPM too. In addition to this, we are securing new and profitable avenues to supply TPM, while developing our own new product lines too – including reaching into the local medicinal and North American recreational edibles markets with a competitive gummy formulation."*

**Entitlement Offer to Shareholders to fund Phase III Clinical Trial for CBD Soft-Gel Capsule**

In April 2023, the Company commenced a capital raise seeking approximately A$11 million. The raise was structured in two parts – an Entitlement Offer to shareholders, followed by a subsequent placement of Shortfall with sophisticated and institutional investors.

Proceeds from the raise will be used to fund Avecho's pivotal Phase III Clinical Trial for its proprietary CBD soft-gel capsule for the treatment of insomnia - the biggest trial of its kind, designed to collect data that will meet the requirements of the Therapeutic Goods Administration ("TGA") and key international regulators.

The Entitlement Offer concluded in May 2023 with ~A$2 million raised from existing shareholders. The initial contribution from shareholders allowed the Company to commence essential manufacturing for its CBD soft-gel capsule product.

The Company has until the 10 August 2023 to allocate any Shortfall.

**Avecho commences CBD soft-gel manufacturing for pivotal Phase III Clinical Trial**

At the conclusion of the Entitlement Offer, the Company commenced manufacturing activities to support its pivotal Phase III Clinical Trial with a new US-based Contract Manufacturing Organisation ("CMO"), Procaps Group.

Procaps Group (NASDAQ: PROC) is a reputable developer of pharmaceutical and nutraceutical solutions, medicines, and hospital supplies across 50 countries globally. Procaps Group has experience in the manufacture of pharmaceutical cannabinoid products and is currently manufacturing US Food and Drug Administration ("FDA") approved dronabinol synthetic tetrahydrocannabinol ("THC") capsules for sale in the USA.

Work undertaken by Procaps Group will include the manufacture of three registration batches of Avecho's CBD capsule. These batches will be placed on formal stability studies to define shelf life of the commercial product. Initial batches of the CBD soft-gel capsule have now successfully passed a two-year stability milestone, indicating it meets pharmaceutical standards. Documentation from these batches is a key component of the registration package to be submitted to regulatory agencies such as the TGA and FDA.

Clinical supply from the Procaps Group will be available in Q3 2023.

**Extended patent protection**

Avecho has established a large patent portfolio protecting all candidate applications of TPM; however, the Company's core intellectual property ("IP") has always been the patent protecting the manufacture of TPM.

In May 2023, the Company announced that the USPTO has allowed its new patent application covering an optimised manufacturing process for TPM. When granted, the US patent is expected to provide Avecho with monopoly rights to Avecho's TPM manufacturing process until approximately December 2037 or later.

This development follows the recent grant of patent rights to the manufacturing process in India, Japan, Mexico, Russia and Singapore, and foreshadows a pathway for patent protection in the remaining jurisdictions where Avecho's patent applications are pending.

**TPM business development agreements**

In May 2023, Avecho secured a licensing and development agreement with Arthur Group to produce a series of optimised cancer drugs solubilised using TPM.

A large number of high potency oncology drugs have poor aqueous solubility and require adverse solvents such as cremophor that deliver a range of adverse side effects. If successful, replacing these solvents with TPM will potentially provide patients with a safer alternative with reduced side-effects.

Under the terms of the agreement, Arthur Group will pay for all formulation, non-clinical and clinical development of the products – and Avecho will receive 30% of revenue from licensing and 30% of net profit from commercialisation of these products.

Arthur Group currently develops and manufactures 23 commercial oncology products. The combined US market size for these commercial oncology products is approximately US$2.92 billion[1].

[1] IQVIA market data 17 May 2023.

The Company's other injectable partner, Athenex Inc ("Athenex"), had previously submitted Avecho's TPM phytonadione (Vitamin K) to the FDA in a pre-IND. Formal FDA feedback stated that the existing toxicology package demonstrating the safety of TPM appeared sufficient to support the use of the TPM in a phytonadione injection – although toxicology reports would need to be examined in more detail to confirm adequacy upon submission of an IND application.

In parallel to the pre-IND, Athenex had been working to spin-out its injectable business, Athenex Pharmaceutical Division LLC. To best facilitate this process, Athenex and certain subsidiaries filed voluntary proceedings under Chapter 11 of the U.S. Bankruptcy Code in the U.S. Bankruptcy Court for the Southern District of Texas. Injectable products maker, Sagent Pharmaceuticals, was successful in the purchase of Athenex's injectable assets in June 2023. Once the acquisition is formally concluded, Avecho will determine whether the TPM injectable phytonadione asset remains of interest to Sagent.

In February 2023, further collaboration was cemented with the Lambert Initiative to focus on the development of topical cannabinoid products, together with the use of Avecho's oral CBD capsule product on novel indications not previously associated with CBD therapy. Avecho's CBD capsules have been provided to the Lambert to facilitate commencement of both trials.

These candidate indications have emerged from pre-clinical and early-stage clinical studies conducted by Lambert Initiative researchers and associates, and represent attractive indications for future CBD products registered as OTC medicines with the TGA.

**Expanding cannabinoid portfolio**

In June 2023, the Company announced it has completed the development of first generation TPM gummies containing cannabinoids. Gummies are chewable, jelly-like preparations made from a mixture of glycerin and gelatin, and can incorporate a range of medications or nutraceutical ingredients.

They have become increasingly popular dosage forms for use with cannabinoids, as they provide an alternative method of consumption to smoking and vaping without the associated respiratory issues. TPM cannabinoid gummies out-perform standard products with faster onset and greater magnitude of effect.

The medicinal applications for CBD gummies are growing rapidly, with neurological and psychiatric disorders a key driver of the CBD gummy market's evolution in North America. Gummies incorporating THC are becoming increasingly dispensed for the management of pain. Both CBD and THC gummies have become major product categories in the North American consumer and recreational cannabis markets.

With the inclusion of edibles, Avecho's current cannabinoid portfolio now contains four different dosage forms – oral oils, oral soft-gel capsules, oral edibles, and topical gels. All products show increased absorption from the inclusion of TPM, which is a key differentiating feature across all dosage forms. Many of these products are already the subject of ongoing licensing discussions.

**Corporate**

During the quarter ended 30 June 2023, the Company had received a sum of ~A$687k from its R&D tax return related to FY22 and a sum of ~A$1.95 million from the non-renounceable entitlement offer. The Company had also received payments totalling ~A$439k from Ashland for Vital-ET sales and an amount of ~A$263k from Perrigo Pharma. In addition, during the quarter the Company invested ~A$403k in R&D activities and incurred administration and corporate costs of ~A$532k. Administration and corporate costs during the quarter were higher compared to historical amounts due to additional insurance, investor relationships and capital raising fees.

At the end of the quarter, the Company held ~A$2.8 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$105K.

**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 2023 |

| **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 | 710 | 710 |
| 1.2 | Payments for | | |
| | (a) research and development | (403) | (480) |
| | (b) product manufacturing and operating costs | 20 | (112) |
| | (c) advertising and marketing | - | - |
| | (d) leased assets | - | - |
| | (e) staff costs* | (295) | (594) |
| | (f) administration and corporate costs | (533) | (543) |
| | (g) patent portfolio costs | (61) | (67) |
| 1.3 | Dividends received (see note 3) | - | - |
| 1.4 | Interest received | 4 | 5 |
| 1.5 | Interest and other costs of finance paid | (6) | (6) |
| 1.6 | Income taxes paid | - | - |
| 1.7 | Government grants and tax incentives | 687 | 687 |
| 1.8 | Other (EMDG) | - | - |
| **1.9** | **Net cash from / (used in) operating activities** | **123** | **(400)** |

**A percentage of staff costs are reallocated to payments for research and development.*

| | | | |
|---|---|---|---|
| **2.** | **Cash flows from investing activities** | | |
| 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 (6 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) | - | - |
| **2.6** | **Net cash from / (used in) investing activities** | **-** | **-** |

| **3.** | **Cash flows from financing activities** | | |
|---|---|---|---|
| 3.1 | Proceeds from issues of equity securities (excluding convertible debt securities) | 1,946 | 1,946 |
| 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 | (111) | (111) |
| 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 | (14) | (35) |
| **3.10** | **Net cash from / (used in) financing activities** | **1,821** | **1,800** |

| **4.** | **Net increase / (decrease) in cash and cash equivalents for the period** | | |
|---|---|---|---|
| 4.1 | Cash and cash equivalents at beginning of period | 924 | 1,468 |
| 4.2 | Net cash from / (used in) operating activities (item 1.9 above) | 123 | (400) |

| Consolidated statement of cash flows | | Current quarter $A'000 | Year to date (6 months) $A'000 |
|---|---|---|---|
| 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) | 1,821 | 1,800 |
| 4.5 | Effect of movement in exchange rates on cash held | - | - |
| **4.6** | **Cash and cash equivalents at end of period** | **2,868** | **2,868** |

| 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 | 2,353 | 924 |
| 5.2 | Call deposits | 515 | - |
| 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)** | **2,868** | **924** |

| 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 | (105) |
| 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**<br>*Note: the term "facility' includes all forms of financing arrangements available to the entity.*<br>*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) | 123 |
| 8.2 | Cash and cash equivalents at quarter end (item 4.6) | 2,868 |
| 8.3 | Unused finance facilities available at quarter end (item 7.5) | - |
| 8.4 | Total available funding (item 8.2 + item 8.3) | 2,868 |
| 8.5 | **Estimated quarters of funding available (item 8.4 divided by item 8.1)** | **N/A** |

*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: 25 July 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.