



ASX Announcement

17 May 2023

Avecho commences CBD TPM[®] softgel manufacturing for pivotal Phase III insomnia study

Highlights:

- Avecho has commenced manufacturing activities for its oral CBD TPM[®] softgel capsule with US-based Contract Manufacturing Organisation, Procaps Group.
- Procaps currently manufactures FDA approved dronabinol (synthetic THC) capsules and is ideally equipped to scale up product manufacturing for Avecho's product for prescription, over-the-counter and consumer sales, in all key global markets.
- Upon the successful completion of its ongoing capital raise to fund the Phase III trial for its CBD TPM[®] softgel product, Avecho will be positioned to commence the pivotal study when product is received from Procaps during Q3.

Melbourne, Australia, 17 May 2023 - [Avecho Biotechnology Limited](#) (ASX: AVE, "Avecho", or "the Company") has today announced it has commenced manufacturing activities to support its pivotal Phase III clinical trial with US-based Contract Manufacturing Organisation ("CMO"), Procaps Group.

Procaps Group (NASDAQ: PROC) is a developer of pharmaceutical and nutraceutical solutions, medicines, and hospital supplies across more than 50 countries and all five continents. Procaps has a direct presence in 13 countries in the Americas where it develops, manufactures, and markets over-the-counter pharmaceutical products, prescription pharmaceutical drugs, nutritional supplements and high-potency clinical solutions. Procaps Group has experience in the manufacture of pharmaceutical cannabinoid products and is currently manufacturing US Food and Drug Administration approved dronabinol (synthetic tetrahydrocannabinol ("THC")) capsules for sale in the USA.

Avecho conducted due diligence on contract manufacturers throughout 2022 to identify manufacturing options able to service both the global pharmaceutical and consumer markets. Manufacturing of Avecho's CBD capsule was transferred to multiple manufacturing candidates and small-scale batches placed on short term stability. Procaps Group demonstrated it could successfully manufacture Avecho's cannabidiol ("CBD") TPM[®] capsule to the existing specifications and performance of the existing product.

Avecho's imminent Phase III study will test the oral CBD TPM softgel capsule for the treatment of insomnia targeting enrol of 540 patients across three treatment groups to compare nightly CBD doses of 75 and 150 mg CBD with placebo over an 8-week dosing period. This will be the largest study of its kind to date.

Procaps Group will be responsible for producing up to 290,000 capsules to support the trial. Avecho recently raised ~\$2M in an entitlement offer to shareholders to support this work.

Avecho CEO, Dr Paul Gavin, said: *"The initial entitlement offer to shareholders raised sufficient capital to kick-off the manufacturing activities associated with our pivotal Phase III trial. We can't commence the trial until the investigational product is manufactured, so raising sufficient capital to commence these activities now while we conclude raising capital was critical. We are delighted that Procaps Group will be joining us on this journey as we prepare for this defining late-stage clinical trial which will be an exciting milestone for our Company and the biotechnology industry at large. Importantly for Avecho, Procaps Group are a manufacturing option for CBD capsules able to be sold in further consumer markets."*



The Procaps Group campaign will also include the manufacture of three registration batches of the CBD capsule. These batches will be placed on formal stability studies to define the shelf life of the commercial product. Documentation from these batches is a key component of the registration package to be submitted to regulatory agencies such as the US Food and Drug Administration and Australian Therapeutic Goods Administration.

The pivotal Phase III clinical trial will commence in Q3 2023, pending the availability of clinical supply from Procaps Group and the allocation of shortfall required to conclude Avecho's current capital raise.

For enquiries, please contact

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Questions related to the announcement are welcome via our [InvestorHub platform](#).

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

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.

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