



## ASX Announcement

9 April 2020

ASX Market Announcements  
ASX Limited  
Level 4  
Stock Exchange Centre  
20 Bridge Street  
Sydney NSW 2000

## Chairman's Address

**Melbourne, Australia, 9 April 2020** – Avecho Biotechnology Limited (ASX: AVE) ("Company"), an Australian drug delivery company, is pleased to provide the Chairman's Address in respect of the Annual Report 2019 and the business performance and outlook. The Chairman's Address will be circulated to shareholders along with the Annual Report 2019, and will also be available on the Company's website on <http://avecho.com.au/investor-centre/>.

As announced on 25 March 2020, the Company also wishes to remind its shareholders that its Annual General Meeting has been postponed. The Company will provide further information when it becomes available.

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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 Health, Animal Health and Personal Care products using its proprietary drug delivery system called TPM<sup>®</sup> (Targeted Penetration Matrix). TPM<sup>®</sup> 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<sup>®</sup> enhanced patches, gels and injectable products for the human health market and is also developing TPM<sup>®</sup> 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.



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Dear Shareholders,

I am pleased to present Avecho's Annual Report for the year ended 31 December 2019.

Following the final arbitration resolution, we have returned our focus to the operating activities of the business and advancing commercialisation of our portfolio of products enhanced by our core TPM® technology. Our focus is on human health.

TPM® is used to enhance the delivery and performance of known drugs. It is a proprietary combination of two forms of Vitamin E, which is able to improve the solubility, absorption and stability of many drugs. TPM® creates products that are safer and more effective, thereby providing better outcomes for patients.

Our strategy is to extract value from the TPM® technology by developing products to a stage where they can demonstrate their technical differentiation and become attractive to potential partners. Avecho has a number of commercially attractive formulations in the pipeline at various stages of development. This includes the late-stage assets of Daptomycin TPM® and a portfolio of other injectables which are ready for partnering.

We have also identified formulation and drug delivery problems in the emerging medicinal cannabis space. We intend to overcome these issues using our TPM® delivery system, creating a differentiated, high-quality, pharmaceutical-grade product with a formal clinical indication. We have recently announced the launch of this program to the market. It already has led to discussions with some of the larger manufacturing partners in the cannabinoid space.

During 2019, we changed our name to Avecho. This is symbolic of a new era for the company. It marks the culmination of a disciplined process to streamline the business and focus on our highest value programs. It was important to us that when we emerged with a new brand, we did so at a time when legacy issues in the business had been resolved. We now have a clear focus and value proposition, and a high-quality portfolio ready for advancement.

## **Business performance and outlook**

### Human Health portfolio

Our core injectables program continues to advance. Working with known injectable drugs that have solubility problems, we have reformulated them using our TPM® technology. TPM® allows us to remove adverse excipients and make safer injectables. It means we can create physician-preferred injectable presentations. We can increase efficiencies in hospital workflow. We can also potentially manufacture products at a lower cost. The inclusion of TPM® enables strong patent protection. The commercial differentiation of the new formulations may also support increased pricing versus generics.

Avecho has a range of formulations at different stages of active development. This provides us with a relatively fast pathway to partnering and the ability to generate value for shareholders. A number of our original injectable formulations concluded their initial two-year stability assessment last year. This has enabled us to confirm that the reformulation work was successful and have engaged in more serious business development discussions on the products.

Our partnership with Terumo Corporation was concluded in October 2019. After a period of assessment, the Propofol TPM® formulation was deemed by Terumo not suitable for long-term infusion, and therefore unsuitable for the Japanese market.

Nevertheless, our partnership with Terumo provided considerable expertise and funding towards multiple TPM® projects. It is important to remember that our technology and programs have advanced through our partnership with Terumo. Indeed, the Propofol TPM® formulation has subsequently been optimised further in the Avecho laboratory. We hope that the second-generation Propofol will be suitable for longer-term infusion. With the conclusion of the Terumo partnership, Avecho will be free to partner this revised Propofol product with other interested parties, including revisiting Terumo.

Following a meeting with the US Food and Drug Administration (FDA), Avecho reached a crucial turning point in the development of the Oxymorphone TPM® patch. The meeting helped us to understand potential FDA concerns around a transdermal oxymorphone patch. In the light of FDA guidance, we have initiated a new business development effort in relation to the patch.

#### Animal Health portfolio

In line with Avecho's strategy to monetise its non-core assets and focus on human health programs, the animal health portfolio is continuing to pursue animal health opportunities only where there is third-party interest and/or funding. A number of our commercial partners continue to evaluate the utility of TPM® in feed and veterinary products for livestock. Performance and proof-of-concept studies are being undertaken by and with these partners. The studies focus on new models to de-risk the respective programs before they enter into commercial agreements. Some of these studies have taken some time, but the cost is borne by the other party and do not distract or utilise Avecho's resources. We will continue to be in discussions with interested parties.

As we have previously reported, our application to the European Food and Safety Authority (EFSA) for TPM® to be utilised as a feed additive to the EU is still under review. We have seen three rounds of questioning by the EFSA and the European Union Reference Lab (EURL). To date, we have only been advised that they have accepted our validated analytical methods, an important part of the approval process. We continue to work with the regulator through this approval process. We will update the market when further formal progress from the regulator is obtained.

#### Oral Cannabinoid Program

Avecho has commenced initial development of an oral cannabinoid product to address the growing pains associated with the medicinal cannabis market.

Avecho's cannabinoid program will develop a pharmaceutical dosage form of our own and will support the benefits of including TPM® in natural medicinal cannabis extracts. This will open additional licensing opportunities for the use of TPM® in third-party medicinal cannabis products, both in Australia and large North American markets.

We believe this is a compelling opportunity for Avecho. Our TPM® technology lends itself particularly well to oral cannabinoid applications. Cannabinoids are lipid soluble molecules with poor aqueous solubility. The limited solubility of lipids leads to poor oral bioavailability, high variability in absorption, and difficulty in developing aqueous dosage forms. The solubility profile of the cannabinoids makes them perfect for use

in combination with TPM®. The early work undertaken by Avecho indicates that the inclusion of TPM® will overcome many of the limitations of cannabinoid dosing that result from their poor solubility.

The rapid expansion of the medicinal cannabis market creates a significant opportunity for Avecho.

It is important to note that medicinal cannabis can be prescribed in Australia today without conducting evidence-based clinical trials and this has created an environment where there is lesser incentive to engage in costly human studies. In the absence of clinical data, there is less evidence proving medicinal cannabis products will work for any given disease indication. Without a labelled indication, medicinal cannabis products will remain as specialty products available through the Special Access Scheme (in Australia).

But, as a company experienced in clinical development, Avecho does not intend to shy away from clinical development. The opportunity for Avecho is to develop a true pharmaceutical cannabinoid, with a clinical indication and formal approval.

This program is already gaining momentum. We look forward to keeping the market informed as this unfolds.

#### Production portfolio

Consistent with the company's strategy to move its focus to its core Human Health business, in June 2019 Ashland Global Holdings Inc. (NYSE: ASH) signed an agreement to purchase global manufacturing rights to Vital ET and TPM® for use in personal care products for a fee of US\$2.5 million (approximately AUD\$3.5 million). Ashland is now the exclusive developer, manufacturer and seller of Vital ET® and TPM® for use in the global personal care products market.

The transaction provides an injection of non-dilutive capital and strengthens our cash position—a positive for Avecho and its shareholders. The agreement brings forward revenue that we expected to accrue over a four-year-plus period. Avecho retains the right to manufacture TPM® for human and animal health applications.

The end of 2019 saw the completion of the important technical transfer of our manufacturing methods to Ashland. This was an important milestone for the company in completing its obligations under the deal. Avecho will continue to supply Ashland with products for its customers in 2020, as required, until their upscaling activities are completed.

#### Financial Review

The revenue was increased by 204% for the year to \$4.2 million (2018: \$1.4 million), mainly attributable to one-time licence fee from Ashland for the global exclusive manufacturing rights to Vital ET® and TPM® for use in personal care products. Expenses from continuing operations were considerably lower at \$3.6 million (2018: \$6.2 million), with significantly lower legal fees and reduction in employment costs.

Cash on hand as at 31 December 2019 was \$3.2 million, which provides sufficient working capital for the next 12 months.

### Conclusion

We have worked hard this year to advance our strong pipeline in injectables and advance an exciting and promising new opportunity in the medicinal cannabis market. With a range of products in the pipeline at various stages of the development, we have multiple opportunities to move forward with partners and advance clinical development, thus further de-risking and adding value to the portfolio.

We thank our shareholders for their ongoing support and look forward to keeping you informed of our progress.