

## **ASX Announcement**

31 May 2021

ASX Market Announcements  
ASX Limited  
Level 4, North Tower, Rialto  
525 Collins Street  
Melbourne VIC 3000

### **Chair's Address & CEO Presentation**

**Melbourne, Australia, 31 May 2021:** Avecho Biotechnology Limited (ASX:AVE, "Avecho", or "the Company") attaches the Chair's Address and the Chief Executive Officer's Presentation for the Annual General Meeting of 31 May 2021.

**- ENDS -**

This announcement is authorised for release by the Board of Directors of Avecho Biotechnology Limited.

#### **Investor + General Enquiries**

Ms Melanie Leydin  
Company Secretary  
Avecho Biotechnology Limited  
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#### **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<sup>®</sup>**). 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 injectable, oral and topical 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)

Dear Shareholders,

Before we enter into the formal business of the meeting, I would like to spend a few minutes reflecting on the progress and events of the year.

This year, as our global community has navigated the public health challenges presented by COVID-19, the biotechnology sector has emerged bright, strong and united in our goal to improve health outcomes. Here at Avecho Biotechnology Ltd (ASX:AVE), we are proud to be part of this community and feel energised by a renewed focus on the importance of clinical research, which is very much part of our DNA.

Our goals are targeted. We are leveraging the capabilities of our TPM® technology to improve health treatments for a variety of conditions, making them more effective. Not just better, but best-in-class treatments, in competitive market segments.

We are now primed for growth. Despite some inevitable delays in research and development in 2020, we are continuing to advance our products, both old and new. Here's a quick summary of our primary focus areas:

- **Cannabinoid program:** This was unveiled to shareholders during 2020 and will remain the focus of our company over the next few years, both for in-house product development and out-licensing of enhanced cannabinoid formulations. We have taken a product from concept to clinical testing within the space of six months and have recently completed the initial development of our finished pharmaceutical dosage form, a 75 mg CBD soft-gel capsule incorporating our TPM® technology, developed with Catalent, a leading global provider of advanced drug delivery technologies.
- **Injectable products:** This is a major component of our ongoing licensing campaign. Most recently, Avecho researchers have revised and optimised our Propofol formulation to improve safety. Toxicity studies confirmed our revised formulation vehicle is now safe for a complete 24-hour infusion – which was a major milestone sought by potential licensees. Our Propofol formulation now sits amongst the other products as a viable licensing opportunity.
- **Business development:** Our licensing campaign, with support from BD professionals, aims to partner our legacy pharmaceutical products. The process has proven long, but we have successfully engaged a number of prospective partners in licensing discussions regarding these assets. Discussions are ongoing, and we remain hopeful our products will find a home for their continued development. Development partners have also continued to assess TPM® for inclusion in animal health applications. As announced this morning, one of these potential partners is AB Vista, who continue to assess the TPM® for inclusion in livestock feed products.

## **Business performance and outlook**

### **Cannabinoid program**

We are pleased by the progress we are making to develop cannabinoid (CBD) products enhanced by our TPM® technology. The cannabinoids contained within medicinal cannabis extracts are lipid soluble molecules with poor oral bioavailability. According to our preliminary research, TPM® increases their absorption, as it has done previously for other lipid soluble molecules.

Increasing the absorption of cannabinoids will allow for differentiated cannabinoid products on market, with greater therapeutic potential and/or reduced cost to patients, which is timely given the changing regulatory landscape for these products in Australia.

We have now entered formal development of our first pharmaceutical cannabinoid product, a CBD soft-gel capsule being developed with Catalent in the United States. This product will enter formal clinical trials, with the first trial being a Phase I clinical trial in Q3 to characterise the absorption profile of CBD in healthy volunteers. Then we plan to take the formulation into pivotal efficacy studies, to support registration of the product with the TGA for an insomnia related indication.

The “fill formulation” encapsulated within the soft-gel is already being prescribed to patients in an observational study for patients undergoing therapy with medicinal cannabis. Exposure to patients in this study will be included in future TGA submissions to support the safety of the product, and will also provide real world feedback on the attributes of the formulation.

## **Injectable products**

Our improved Propofol TPM® formulation has now successfully passed critical safety studies, supporting its use for continuous 24 hour infusion.

Following a set-back with our prior formulation, this latest development reinstates promising commercial prospects for our Propofol TPM® formulation for use as a general anaesthetic for the induction and/or maintenance of sedation during surgical procedures.

Our immediate priority now is to partner the product in order to facilitate its continued commercial development.

## **Business development**

This year we also announced the commencement of an external business development campaign, aimed at partnering products from our existing pharmaceutical portfolio. This has reinvigorated a number of promising discussions with potential licensees for products within our portfolio, and albeit a considered process, we are making progress here too.

## **Financial Review**

Avecho recently successfully raised \$5.06m by Placement, which was oversubscribed with more than \$23M in bids. We received strong support from our existing shareholders, together with new sophisticated and professional funds too. At the end of the first Quarter, the company held \$5.7m in cash.

These funds will be used to advance Avecho’s CBD soft-gel development at Catalent, advance the clinical cannabinoid program toward pivotal Phase III studies, and conduct the regulatory work required for potential drug registration.

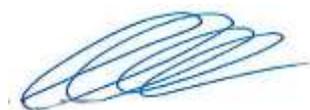
With a strong balance sheet secured, we look forward to a period of focused work to advance the CBD soft-gel product.

## **Conclusion**

We are working hard to deliver outcomes across our primary business portfolios. The Avecho team is talented and hard-working, and supported by a respected network of collaborating research and licensing partners. We have had a very successful 12 months and are looking forward to the year ahead.

Thank you for your continued support and we look forward to keeping you updated with our progress throughout the year.

Dr Greg Collier



Avecho Biotechnology Ltd Chairman

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# Annual General Meeting

Monday, 31<sup>st</sup> May 2021  
At 1:00pm



[www.avecho.com.au](http://www.avecho.com.au) | ASX:AVE

# Safe Harbour Statement

*This presentation, and any representations made before, during or after the presentation, may include forward-looking statements that are inherently subject to risks and uncertainties. These statements relate to, but are not limited to: (1) the safety or efficacy of, or potential applications for, Avecho's TPM<sup>®</sup> platform technology; (2) the strength of Avecho's intellectual property; (3) the timelines for Avecho's clinical trials and regulatory processes for its different products; (4) the scalability and efficiency of manufacturing processes; (5) revenue projections, market share expectations, share price expectations and capital requirements.*

*Actual results may differ from the expectations expressed in these forward-looking statements, and the differences may be material (whether positive or negative). The risks that may cause Avecho's actual results, performance or achievements to be materially different from those expressed or implied by such forward-looking statements, include but are not limited to: (1) risks inherent in the development, approval and commercialization of potential products; (2) uncertainty of clinical trial results or regulatory approvals or clearances; (3) changes to market trends or government laws or regulations; (4) the potential need for future capital; (5) dependence upon collaborators; and (6) protection of intellectual property rights, among others. Accordingly, you should not place undue reliance on these forward-looking statements.*

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Year in review



# Strategic Focus Presented June 2020

Avecho has a clear, strategic focus to deliver on two fronts:

Realise value from its portfolio of existing human and animal health assets

- Minimal investment going forward
- Active business development effort
- Focus on deals that provide near-term cash
- Multiple assets to license

Leverage its proprietary TPM<sup>®</sup> platform to develop new cannabinoid-based pharmaceuticals

- TPM<sup>®</sup> is ideal for formulating cannabinoids
- Allows the creation of highly differentiated products
- Will address long term needs of medical market

# Business Development – (Human Health Assets)

Engaged an external BD licensing firm (Simon Bennett and Associates; SBA) in July last year, to run an external business development and licensing campaign on the legacy human health products

Outreach identified a number of companies with interest in various products within the portfolio. These included propofol, daptomycin, Vitamin K, diclofenac gel, and the oxycodone and oxymorphone patches.

Interest covered a wide range of specific countries and broader territories.

Due diligence was initiated by a number of companies and is still ongoing.



# Business Development – (Animal Health Assets)

TPM<sup>®</sup> has shown promise as an additive to feedstock:

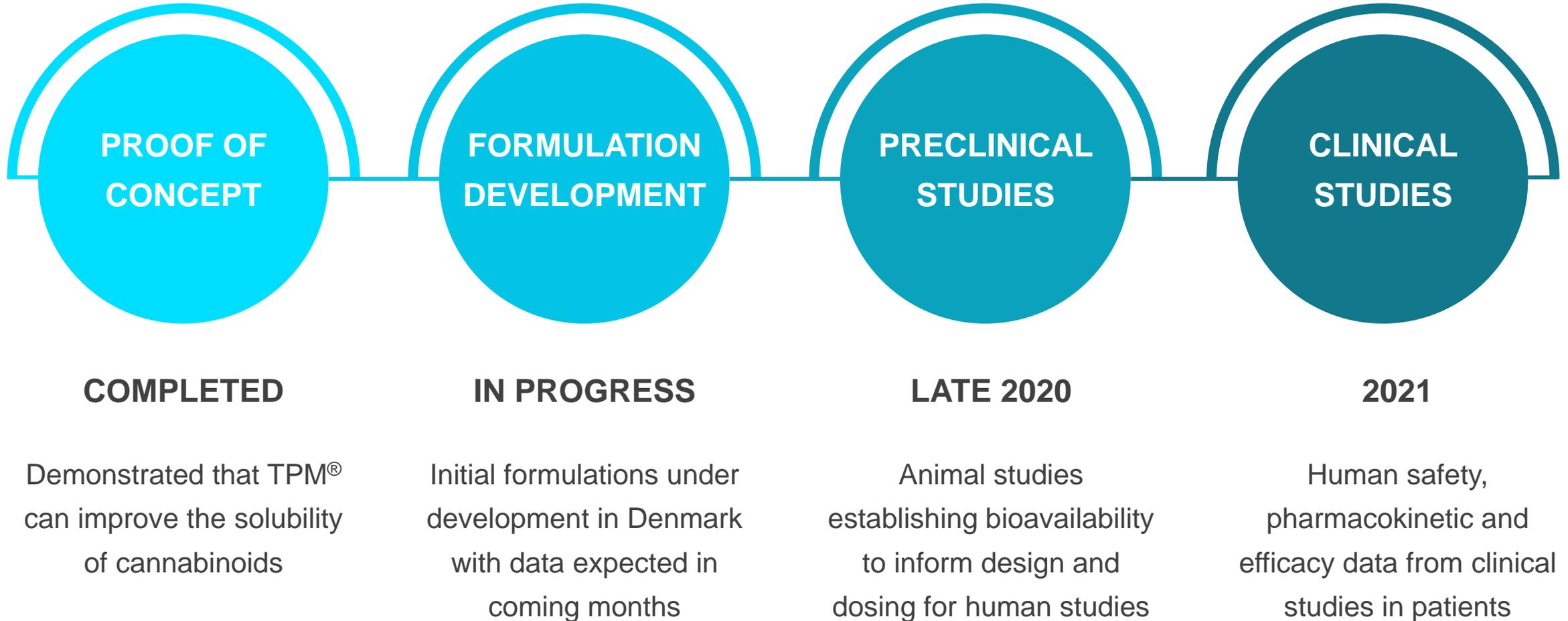
- improves feed efficiency for faster weight gain and stock turnover
- improves meat quality and potential shelf life
- can improve animal health and disease resistance
- is a non-antibiotic alternative to banned antibiotic growth promoters

AB Vista currently undertaking evaluation studies using TPM<sup>®</sup> prior to initiating commercial licensing discussions

- Conducting animal studies using TPM<sup>®</sup> in combination with other ingredients for the management of diarrhoea in swine
- Avecho has retained manufacturing rights for Animal Health uses



# 2020 Plan for developing TPM<sup>®</sup> formulation of cannabinoids



# TPM formulations increase oral bioavailability of CBD

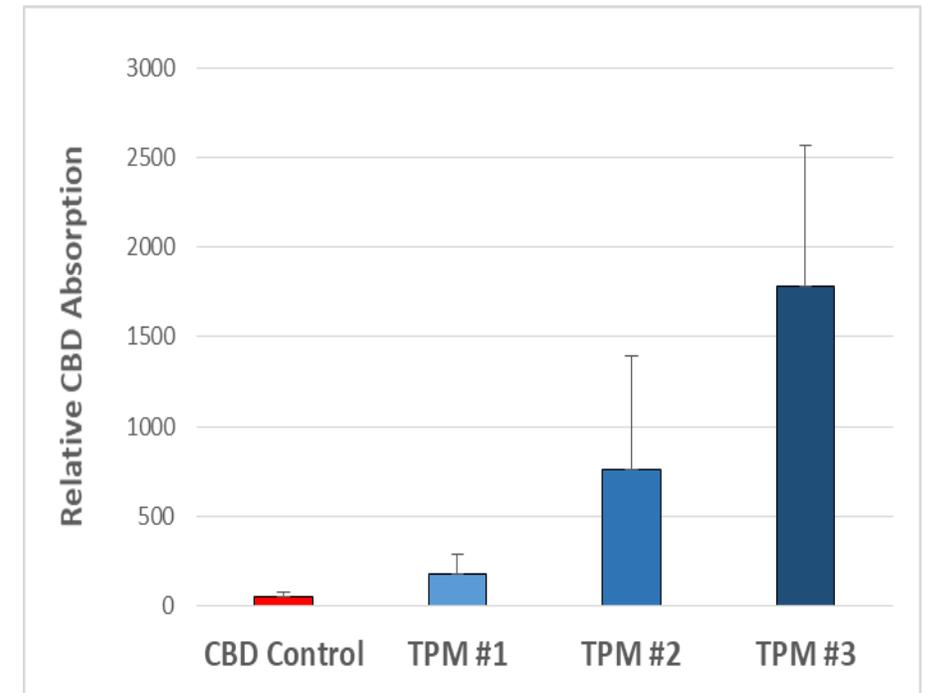
Research conducted at Bioneer:FARMA in Copenhagen

Rats received a single oral dose of CBD and drug content measured in the blood over time. Absorption from TPM formulations compared against CBD in MCT (as sold to patients).

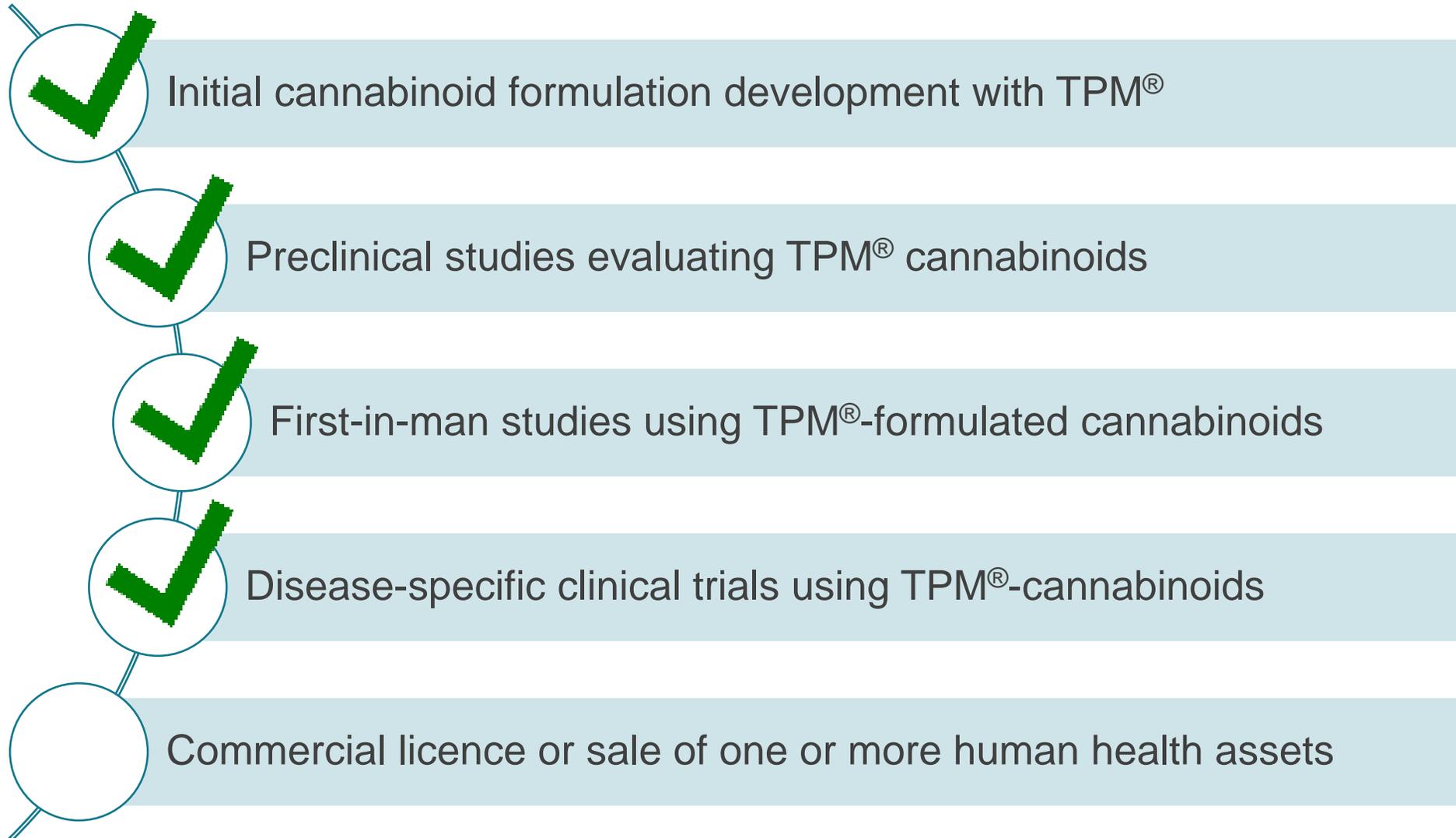
- ✓ All TPM® formulations produced higher mean AUC and Cmax than the commercial CBD formulation.
- ✓ Increases in AUC produced by TPM formulations ranged from **~4-40 times**
- ✓ These increases were statistically significant for the best performing TPM formulations.

TPM® formulations to be taken forward into clinical trials

Total CBD absorbed (AUC)



# 12 Month News flow communicated in June



# Company Snapshot

Shares	1,829M
Market cap	\$31.1M
Options / Performance Rights	217.3M
Cash	\$5.74M <sup>1</sup>
Capital Raise	\$5.06M
230M new shares at 2.2c per share Attached options 1:2, exercisable at 3.5c	
9.67% discount to 5-day VWAP	
\$1M investment from Horizon-3 Biotech	

<sup>1</sup> Quarter ending 31 March 2021



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# CBD soft-gel development

Next 12 months



# TGA Changes - Over-the-counter CBD

In December 2020, the TGA advised that it would allow future CBD products to be registered as over-the-counter (S3) medicines. This would allow patients to buy CBD products directly from a pharmacy, without the need to consult a GP and get a prescription.

However, S3 registration will only be possible for;

- Products registered on the ARTG – pharmaceutical products with proven safety and efficacy
- Oral, sublingual or transmucosal products with a maximal daily dose of 150mg
- Indications that can be self diagnosed and do not require medical supervision.

The maximal daily dose created concern in the space, as it still wasn't clear whether a CBD dose of 150mg would prove to be efficacious in randomized, placebo controlled clinical trials.

The criteria for S3 products appear tailor-made for a CBD product with increased absorption that was already heading for formal clinical trials and product registration.

Products achieving S3 registration will command a unique commercial opportunity within Australia's medicinal cannabis space.

# Oral Pharmaceutical CBD Soft-gel Product

- 75 mg CBD TPM soft-gel capsule developed at Catalent
- Supports single dose or twice daily dosing under TGA S3 framework
- Soft-gel capsules to be tested in Phase I PK study
- Followed by pivotal Phase III study in Australia
- Focusing on insomnia related S3 indication
- Registration with TGA in Australia to follow.



**Enhanced CBD product to be taken into other territories/markets/indications with partnerships**

# Work required to support TGA registration

A registration dossier for product approval in Australia (and other territories) contains data related to the following categories;

- **Chemistry, manufacturing and controls (CMC)** – can the finished product be manufactured reproducibly, to high pharmaceutical standard, with sufficient stability to support a 1-2 year shelf life.
- **Safety** – is the product safe to consume under the labeled dosing conditions
- **Efficacy** – is the product proven to work versus placebo in randomized clinical trials for the labelled indication.

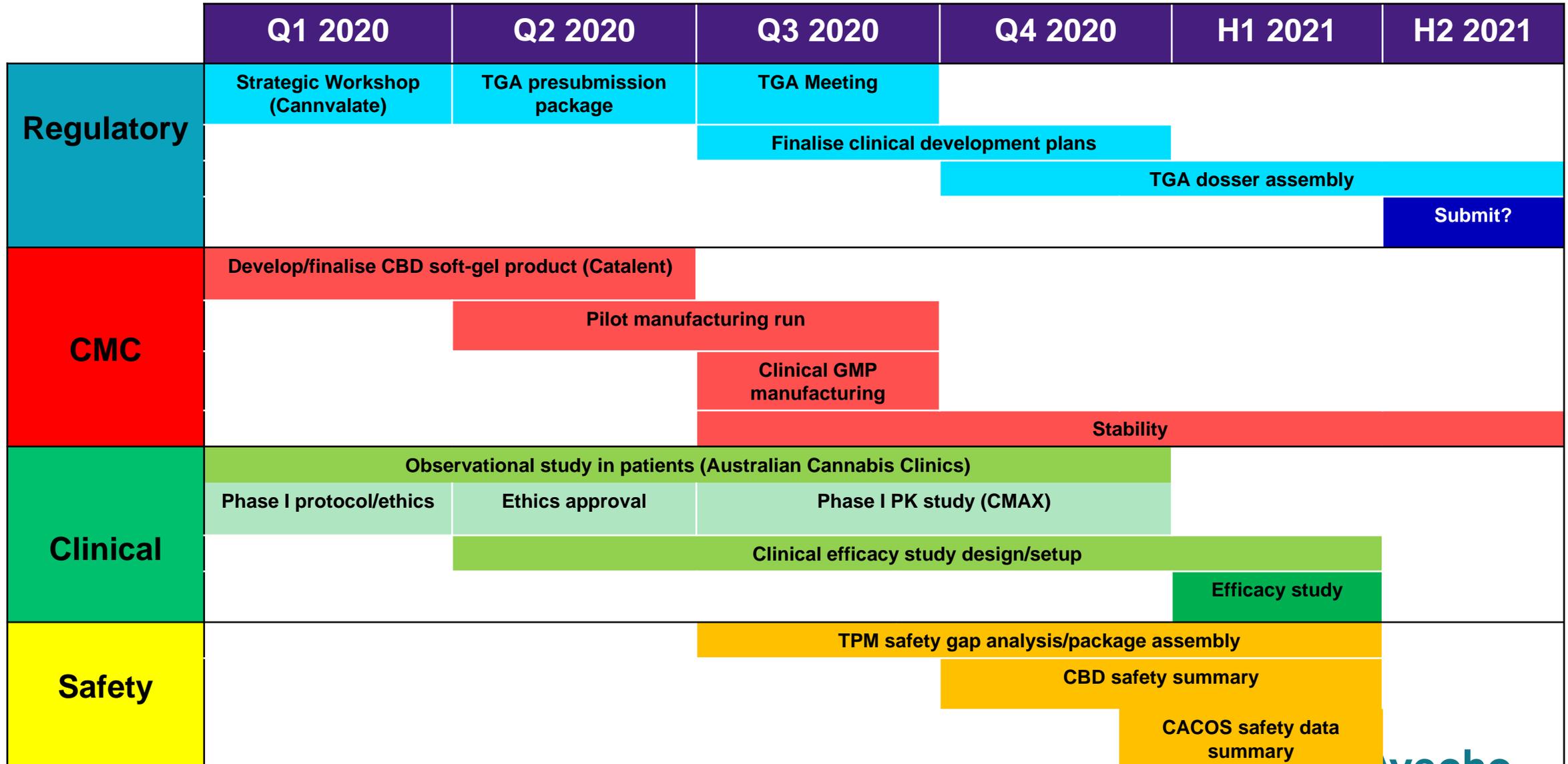
**Regulatory** work underpins each of the above data packages, allowing the data to be honed and presented in the most appropriate way for efficient product registration.

Avecho have begun all of the disciplines above to support the final product registration.

# Ongoing and planned development activities

Regulatory	<ul style="list-style-type: none"><li>• Development plan assembled for work required to register CBD soft-gel</li><li>• TGA pre-submission meeting planned to validate development plans</li><li>• Cannvalate/MCRC engaged to assemble pre-submission package.</li></ul>
CMC	<ul style="list-style-type: none"><li>• Catalent finalised development of initial CBD soft-gel formulation</li><li>• Heading into GMP manufacturing of product to support clinical campaign</li><li>• Formal stability studies</li><li>• Work form the pivotal piece of CMC dossier.</li></ul>
Clinical efficacy	<ul style="list-style-type: none"><li>• Phase I PK study – single dose cross-over to characterise drug absorption</li><li>• Pivotal efficacy study – Randomised clinical trial versus placebo in sleep indication</li></ul>
Safety	<ul style="list-style-type: none"><li>• Safety package on both CBD and TPM</li><li>• CACOS observational study used in support</li></ul>

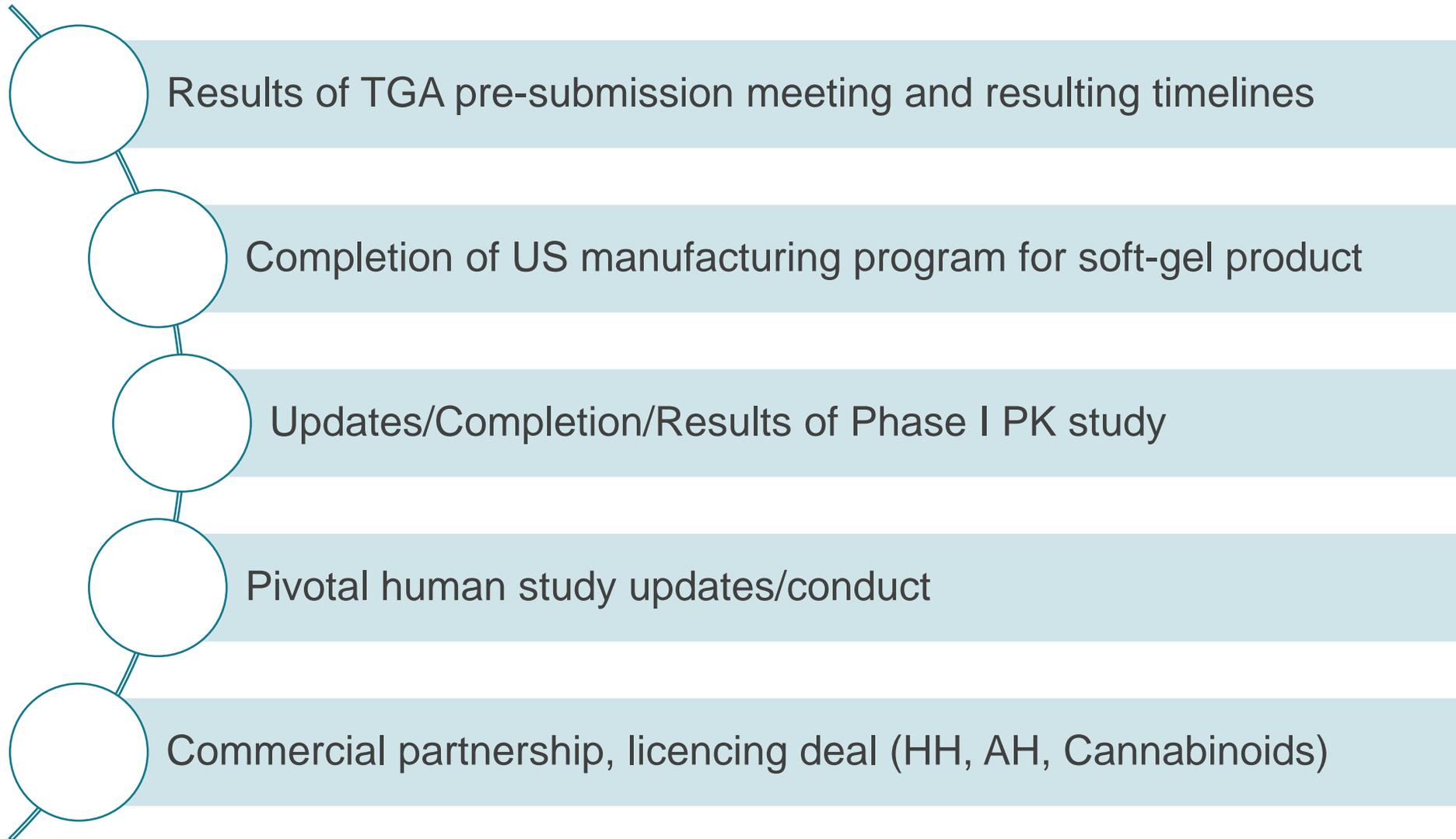
# Broad timelines by activity



# Additional opportunities with third parties

- **Topical cannabinoid products;** Interest in topical cannabinoid products from a growing number of companies/institutes. We have already shown TPM can increase the topical absorption of CBD.
- **Partnerships (academic and commercial);** Providing TPM/cannabinoid combinations to academics with expertise in specific indications of interest (mental health, sleep, pain, cardiovascular, cancer). Specific interest for indications where TPM has been shown to independently have value.
- Partner with companies looking to explore new dosage forms or indications.
- **Explore licensing in other territories/markets for CBD formulation;** US, Europe, UK, etc.

# 12 Month News flow related to primary program



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Questions



# Contact

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