



ASX Announcement

15 June 2020

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

Avecho Investor Update

Melbourne, Australia, 15 June 2020 – Avecho Biotechnology Limited (ASX: AVE) (“Company”), an Australian drug delivery company, advises that a virtual presentation for investors and analysts will be held by webinar on Friday, 19 June 2020 at 11:00am AEST. The Investor Update presentation is annexed to this announcement.

You can register for the Company’s webinar using the following link:
https://us02web.zoom.us/webinar/register/WN_UMp081B4TiqDRlIfq2eDcA

Registered participants will receive a confirmation email containing the Zoom access link, as well as alternative dial-in details if you wish to join by phone.

For enquiries, please contact

Paul Gavin
Chief Executive Officer
+61 3 9692 7222

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®. 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. New additions to the development program include the recently announced application of TPM® to cannabinoids.

See more here - avecho.com.au

Avecho

June 2020

Avecho Investor Update

Non-confidential Presentation



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[®] 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.

Introduction



Paul Gavin – Chief Executive Officer

- Joined Avecho in 2002
- Chief Scientific Officer since 2012, part of company's leadership team since 2009
- Global coordination and management of AVE's pharmaceutical development programs
- An inventor of the TPM[®] platform technology
- BSc(Hons) and PhD in Biochemistry & Molecular Biology from Monash University



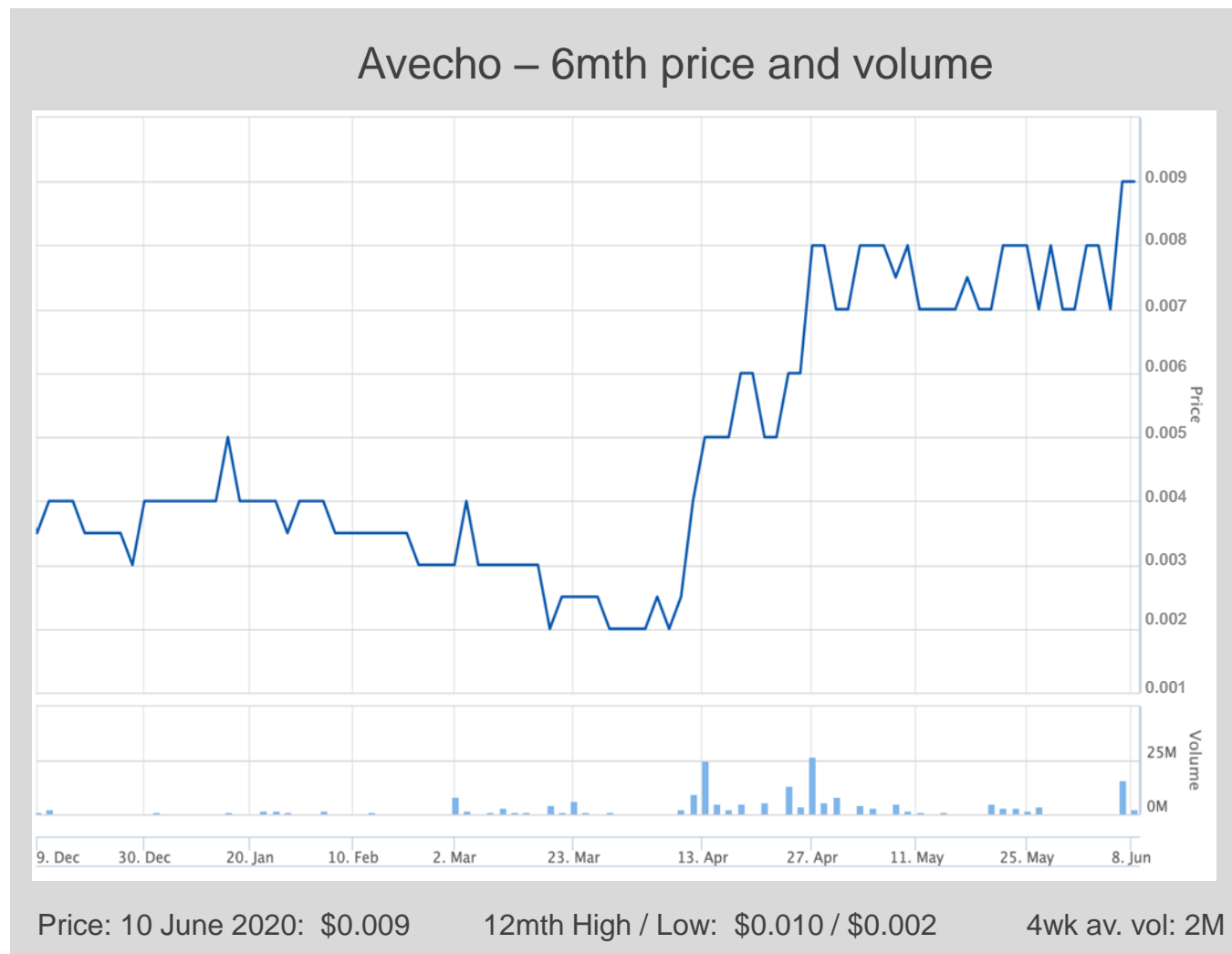
Roksan Libinaki – Chief Operating Officer

- Joined Avecho in 2001
- General Manager of Animal Health & Production
- Managed Avecho's manufacturing business
- BSc(Hons) and PhD in Biochemistry & Molecular Biology from Monash University
- Global Executive MBA from Monash Business School

Company Snapshot

Shares	1,577M
Market cap	\$14M
Options	3.8M
Cash ¹	\$3.0M
Last qtr gross burn ¹	(\$0.5M)
Headquarters	Melbourne
Board	Greg Collier (Chair) Ross Murdoch (NED) David Segal (NED) Matt McNamara (NED)
Substantial shareholders	Mark Kerr (12.7%)

¹ Quarter ending 31 March 2020



Avecho Management & Board



Dr Paul Gavin
Chief Executive Officer

- 18yrs Avecho
- pharma development
- TPM® inventor



Dr Roxsan Libinaki
Chief Operating Officer

- 18yrs Avecho
- animal health development
- TPM® manufacturing



Melanie Leydin
CFO and Company Secretary

- 23yrs accounting
- Inst. of Chartered Accts
- Director Leydin Freyer



Dr Greg Collier
Chairman

- 20+yrs biotech exec experience
- ex-CEO Chemgenex (sold \$200M+)
- 150 publications, 33 patents
- Roche Award for Excellence



Dr Ross Murdoch
Non-Executive Director

- 25+yrs biotech exec experience
- CEO Tasmanian Alkaloids
- ex-CEO Avecho (2015-2019)
- ex-SVP Shire Pharmaceuticals



David Segal
Non-Executive Director

- 30+yrs experience stockbroking
- shareholder in AVE since 1999
- previous IR manager for AVE



Matt McNamara
Non-Executive Director

- 30+yrs experience healthcare
- 20+yr venture capital
- previous CIO Bioscience Managers

Overview of Avecho's TPM[®] technology

TPM[®] is a proprietary combination of two forms of phosphorylated vitamin E

TPM[®] is a unique excipient that encapsulates drug molecules

TPM[®] has been used to formulate drugs to improve their:

- solubility
- stability
- oral bioavailability
- transdermal delivery
- pharmacokinetic profile

TPM[®] has an excellent safety profile making it ideal for drug reformulation

TPM[®] reformulated drugs have:

- improved pharmaceutical properties and performance
- provide opportunities to secure additional patent protection

Propofol TPM[®]



With TPM[®]



Without TPM[®]

Strategic Focus

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[®] platform to develop new cannabinoid-based pharmaceuticals

- TPM[®] is ideal for formulating cannabinoids
- Allows the creation of highly differentiated products
- Will address long term needs of medical market

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Human and Animal Health



Overview of Human Health Assets



Priority

Priority products for licensing with the aim to secure a commercial deal for 1 or more of these products over the next 12 months

- Daptomycin TPM[®]
- Propofol TPM[®]
- Vitamin K TPM[®]

Prospective

Assets ready for ongoing business development effort and presentation to potential partners over the next 12 months

- Oxycodone TPM[®] patch
- Oxymorphone TPM[®] patch
- TPM[®] injectable portfolio
- Diclofenac TPM[®]
- TPM[®]

Daptomycin TPM[®] - Partnering Opportunity

Daptomycin is an antibiotic that became generic in 2016 which is used for the treatment of Methicillin-Resistant Staphylococcus aureus (MRSA)

US sales of daptomycin were US\$700M in 2018 with \$465M coming from the sale of generics (\$205M Teva, \$180M Fresenius, and \$80M others)

While daptomycin is more efficacious than vancomycin for treating MRSA, its adoption has been constrained by reconstitution and stability issues

Formulation with TPM[®] addresses these reconstitution and stability issues providing an opportunity to secure market share with a superior product

Product development is advanced with minimal work required to compile a New Drug Application package for submission to the FDA

Drug	Reconstitution	Stability – room temp	Stability - fridge
Daptomycin	> 30min	12hr	48hr
Daptomycin TPM[®]	< 10min	24hr	72hr



Propofol TPM[®] - Partnering Opportunity

Propofol is an intravenous anaesthetic used for general anaesthesia in surgical patients, with a global market of ~\$1Bn USD

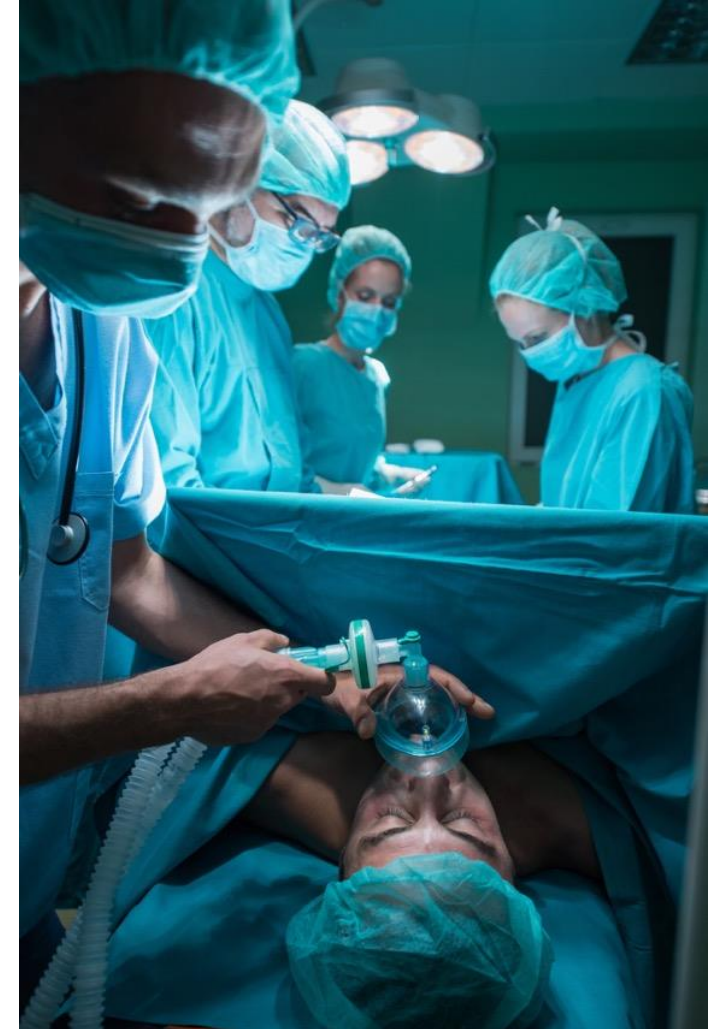
Propofol is an oil which has been formulated as an opaque emulsion comprising of 1% drug in 10% soya oil plus water

While effective as an anaesthetic, this formulation of propofol is:

- opaque, making quality control/quality assessment difficult
- susceptible to microbial growth after contamination
- an emulsion that is unstable and can separate
- forms lipid droplets that may result in pain at the site of injection

Avecho has developed a TPM[®] formulation of propofol which is a clear microemulsion

Avecho has recently refined its formulation to allow for 24hr infusion. This formulation has resumed toxicology testing.



Vitamin K TPM[®] - Partnering Opportunity

Vitamin K is an essential factor required for blood clotting and is administered to:

- all newborns to prevent vitamin K bleeding deficiency (VKBD)
- adults with coagulation disorders resulting from vitamin K deficiency or interference

Global sales of Vitamin K were US\$374M in 2019 and are forecast to grow to US\$640M by 2026

As Vitamin K is insoluble in water, commercial formulations in most markets contain Cremaphor[®] or Polysorbate 80; both which can cause potentially lethal adverse reactions

Avecho has developed formulations of Vitamin K using TPM[®] which are:

- free of problematic excipients (Cremaphor, Polysorbate 80, Lecithin)
- stable for 2yrs
- suitable for dosing paediatric (2mg/ml) and adult (10mg/ml) patients

These formulations may only require a single animal toxicity study and a single human bioequivalence study to support applications for regulatory clearance



Other Human Health Assets – Partnering Opportunities

Product	Opportunity	Status
Oxycodone TPM® patch	Transdermal patch providing sustained pain relief with reduced side effects	Steps required for US filing established
Oxymorphone TPM® patch	Transdermal patch sustained pain relief with reduced side effects	Pre-IND meeting with FDA completed, steps required for US filing established
Diclofenac TPM® gel	Faster pain relief with longer duration	Sold in India under license by Novartis India/Themis Medicare. Regulatory approvals pending in 16 other markets
TPM® Injectables	Broader dosing options and elimination of problematic excipients	Reformulation and 2yrs stability studies completed
TPM®	Manufacturing rights for Human Health applications available for licensing or sale	Human health manufacturing owned by Avecho

Animal Health

TPM[®] 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

Multiple parties currently undertaking evaluation studies using TPM[®] prior to initiating commercial licensing discussions

- Avecho has retained manufacturing rights for Animal Health uses

Application for use of TPM[®] as a feed additive under review with the European Food Safety Authority (EFSA)

No further investment or development planned



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Cannabinoid Pharmaceuticals



Cannabinoid-based Pharmaceuticals

In the past decade, there has been a transformational shift resulting from a recognition of the therapeutic potential of cannabis and cannabis extracts

The majority of countries around the world have recently enacted legalisation permitting the use of cannabis extracts for medicinal purposes

Due to the previous illegal nature of cannabis, R&D into its medicinal uses has been minimal resulting in:

- limited data on its therapeutic benefits and risks
- limited development of suitable formulations and delivery formats
- poor integration in existing healthcare practices

The majority of medicinal cannabis products currently being prescribed are based on botanical material or plant extracts, both of which can be highly variable

In the longer term, patients and doctors will require pharmaceutical products



Potential use in multiple therapeutic areas

Data from available clinical studies supports the use of cannabinoids for a range of different medical conditions

Conclusive or substantial evidence

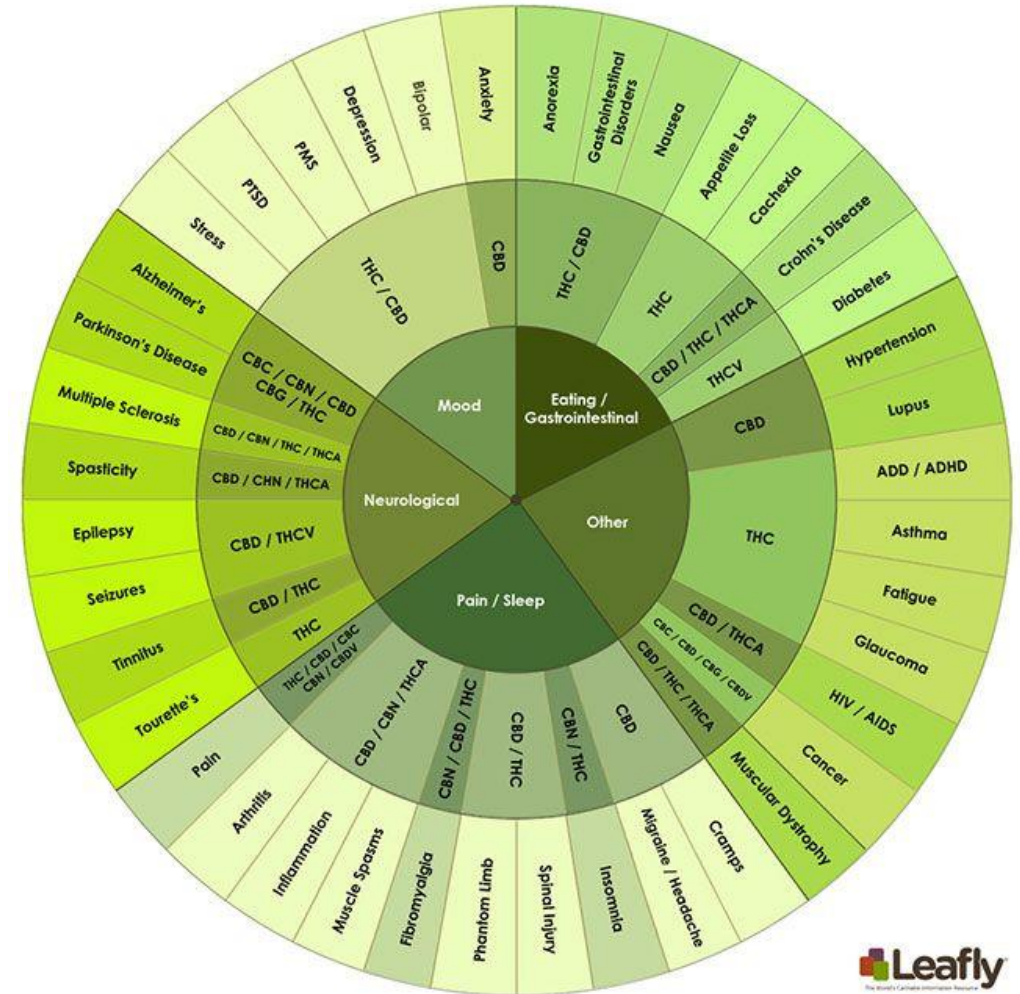
- chronic pain
- chemo-induced nausea and vomiting
- multiple sclerosis spasticity
- treatment-resistant seizures in children

Moderate evidence

- improves sleep disrupted by medical conditions

Limited evidence

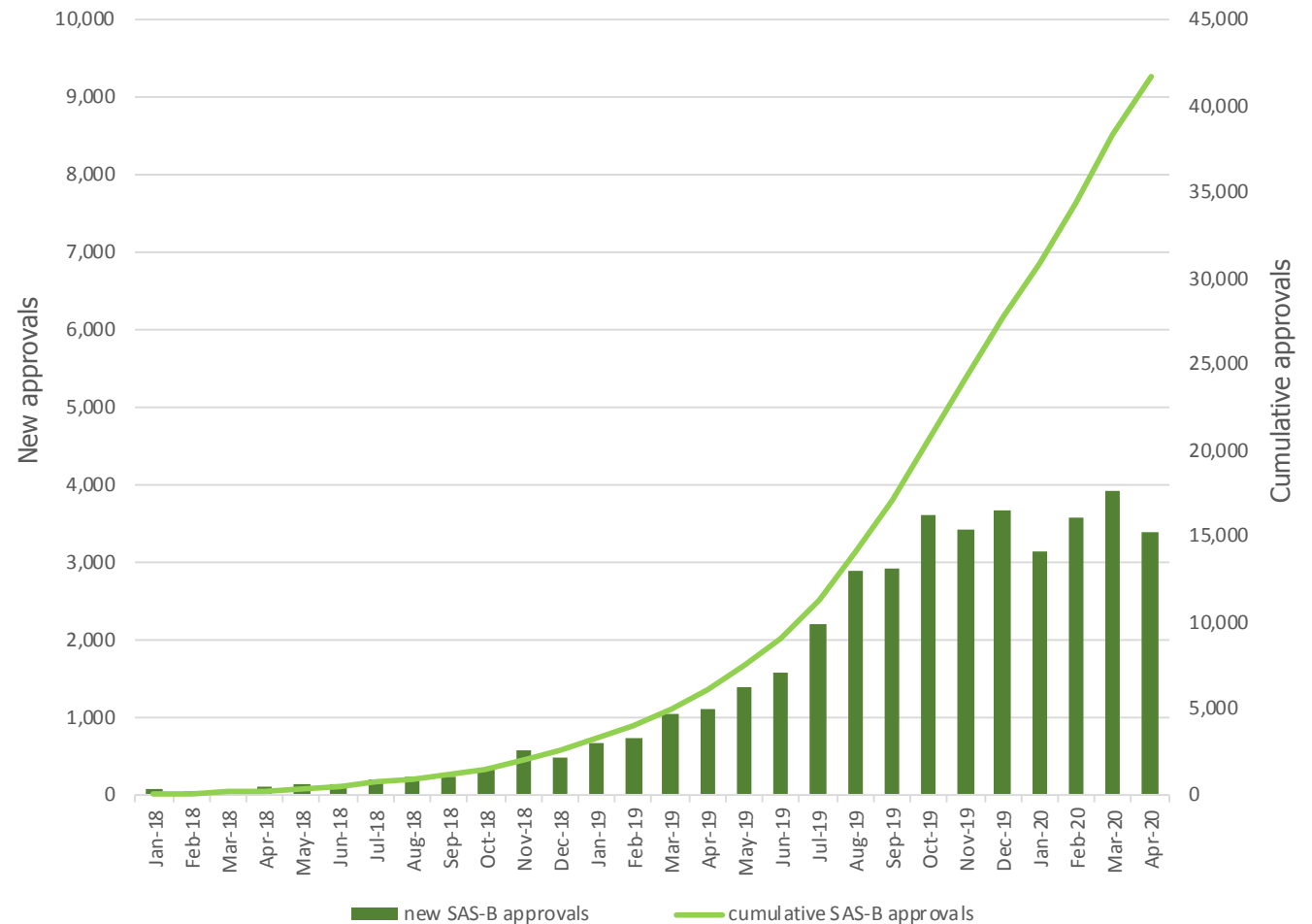
- appetite/weight loss associates with HIV/AIDS
- Tourette syndrome
- reducing anxiety symptoms
- improving post-traumatic stress disorder (PTSD)



Potential use in multiple therapeutic areas

- In more mature markets (Canada, Colorado and California), around 1-2% of the population use cannabis products for therapeutic purposes
- In Australia, this would equate to 250,000-500,000 potential patients that could benefit from using therapeutic cannabis products
- Fresh Leaf Analytics¹ estimates there were ~10,000 active Australian patients in Dec-2019
- As cannabis products are not registered as medicines in Australia, patients currently have to pay for them out-of-pocket
- Australian patients are currently paying \$250-400/mth to access cannabis products

Australian approvals for medicinal cannabis prescriptions²



¹ Fresh Leaf Analytics Q1 2020 – Australian Medicinal Cannabis Market

² <https://www.tga.gov.au/access-medicinal-cannabis-products-1>

Medical market likely to focus on pharmaceutical products

Pharmaceutically developed products are expected to dominate the medical cannabis market in the long term:

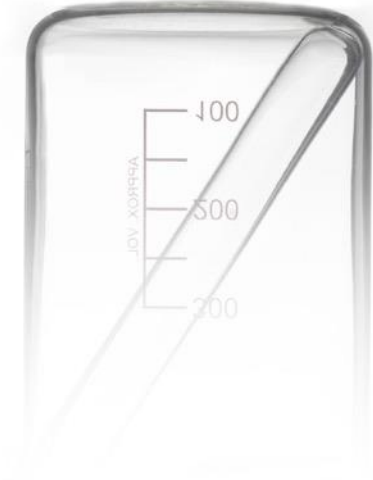
- standardised pharmaceutical delivery formats
- clinical safety and efficacy data
- registered products are physician preferred

Patient registrations have typically slowed, and even declined, in markets following the legalisation of consumer use of cannabis:

- many patients self-diagnose / self prescribe
- precise dosing and cannabinoid profile not critical for many indications
- flexible delivery format (vaping, edibles) possible for some patient groups

Long term, the medical market is expected to comprise of premium-priced, pharmaceutical-type products targeting:

- specific indications
- specific patient groups, such as pediatric or elderly patients
- patients on other medications or who have other contra-indications
- conditions that require precise or specific dosing



TPM[®] is ideal for pharmaceutical formulation of cannabinoids

Cannabinoids (the key active compounds in cannabis) are oil soluble molecules with low solubility in water

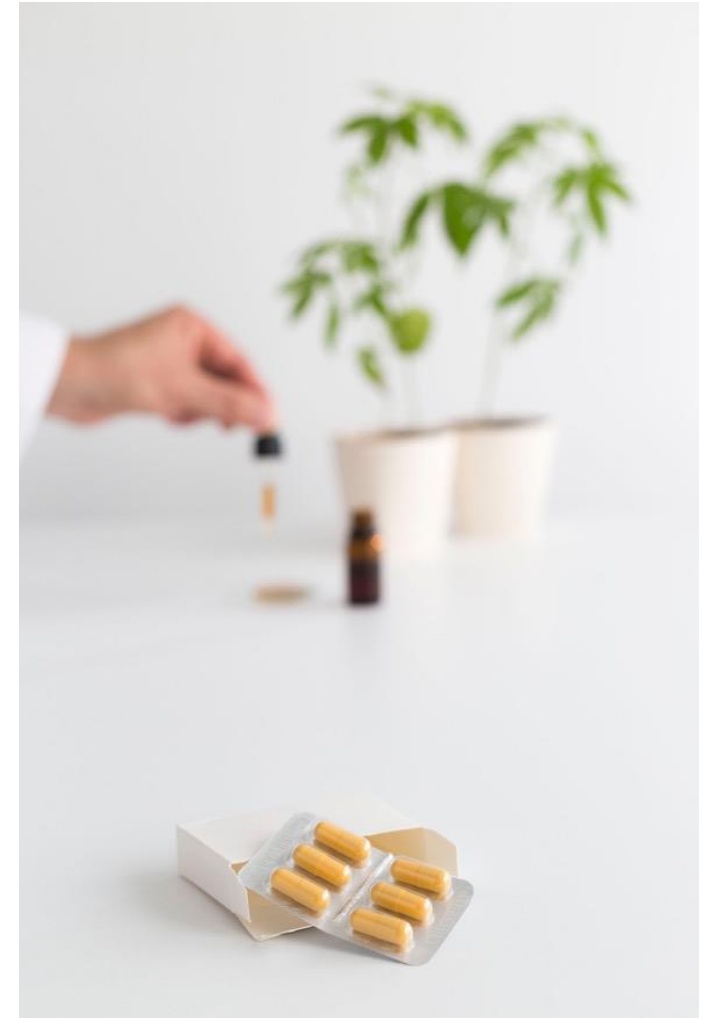
Oil soluble molecules have poor oral bioavailability, which is also true for cannabinoids (3-8% absorbed)

This presents challenges for developing formulations that can deliver cannabinoids to the body efficiently

With other oil soluble molecules, formulations with TPM[®] have:

- increased aqueous solubility – allowing new dosage forms
- improved bioavailability and absorption – better therapeutic profile
- allowed optimisation of pharmacokinetics – speed and duration of affect
- increased stability - major issue with current cannabis oils and extracts

TPM[®] provides Avecho with an opportunity to develop proprietary, cannabinoid pharmaceuticals which perform better than other medicinal cannabis products



Focus is on developing pharmaceutical cannabinoid products

Avecho intends to use TPM[®] to develop cannabinoid-based pharmaceuticals:

- with known and consistent dosing
- delivered in a familiar, pharmaceutical format
- backed by robust clinical evidence
- able to be manufactured at scale

Taking a pharmaceutical approach for cannabinoid-based medicines:

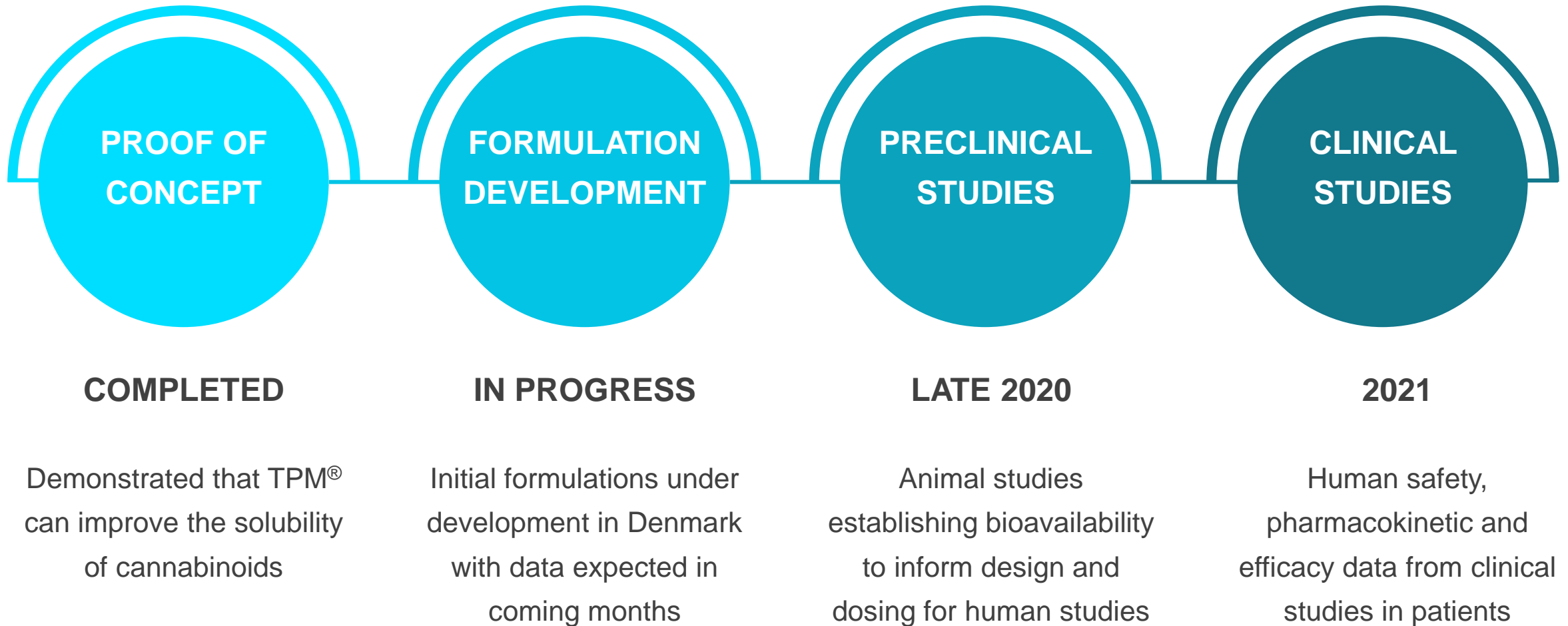
- integrates with current medical practices
- supports potential registration and payment coverage
- less vulnerable to competition from consumer products

Avecho is currently evaluating both purified cannabinoids and extracts for use as active ingredients in its cannabinoid-based pharmaceuticals:

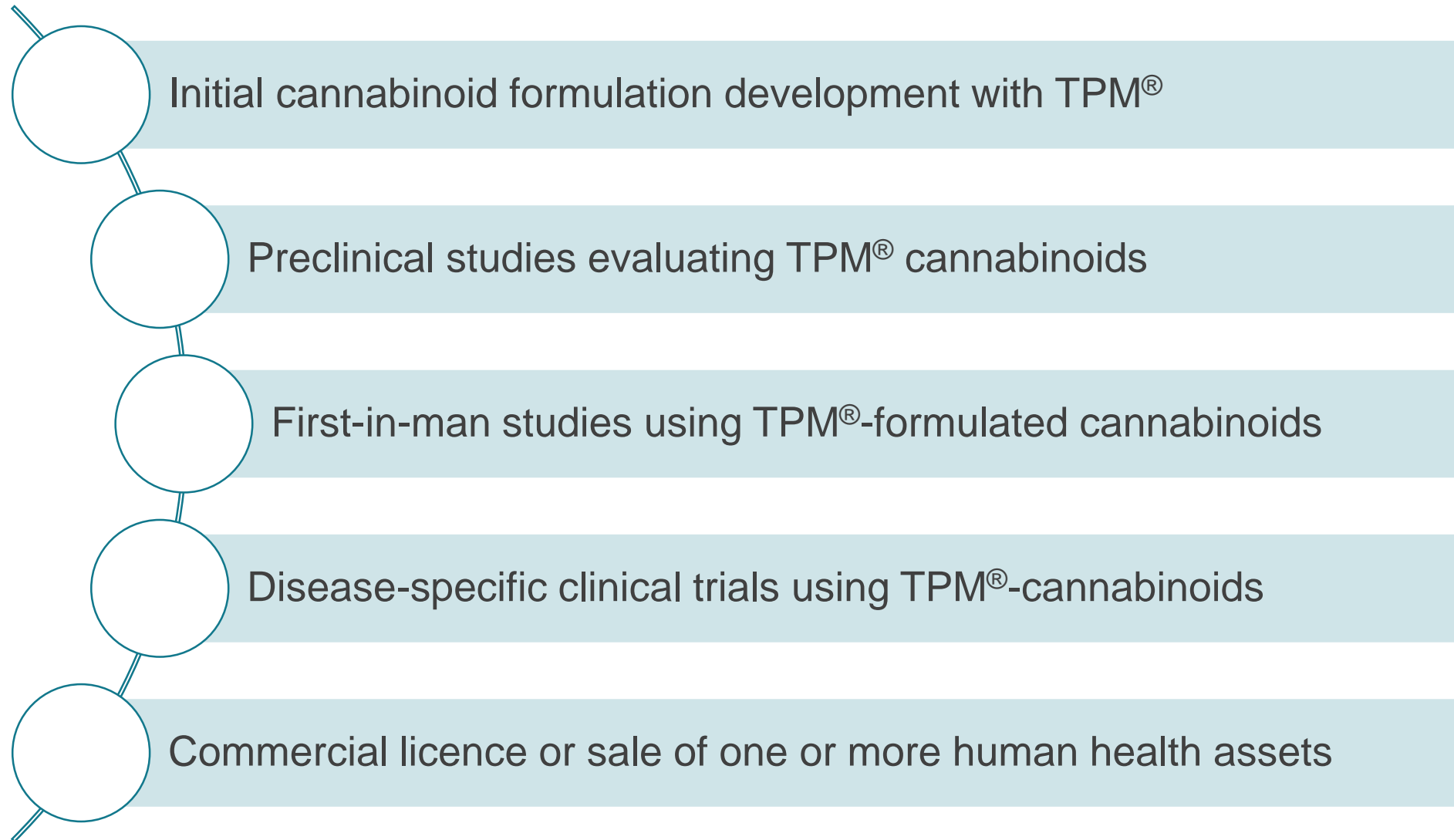
- pure synthetic cannabinoids – supply agreement with PuriSys
- cannabinoid extracts – supply agreement with Tasmanian Alkaloids



Plan for developing TPM[®] formulation of cannabinoids



Anticipated news over next 12 months



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