ASX Announcement

4 December 2019

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

Injectable Portfolio Update: Products Differentiated by TPM®

Melbourne, Australia, December 4, 2019 – The Board of Avecho Biotechnology Limited (ASX: AVE), an Australian drug delivery company, is pleased to provide its stakeholders with an Injectable Portfolio Update: Products Differentiated by TPM®.

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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® (Targeted Penetration Matrix). 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 patches, gels and injectable products for the human health market and is also developing TPM® to enhance the feed efficiency and health of livestock.

Inherent Risks of Investment in Biotechnology Companies
There are a number of inherent risks associated with the development of pharmaceutical products to a marketable stage. The lengthy clinical trial process is designed to assess the safety and efficacy of a drug prior to commercialisation and a significant proportion of drugs fail one or both of these criteria. Other risks include uncertainty of patent protection and proprietary rights, whether patent applications and issued patents will offer adequate protection to enable product development, the obtaining of necessary drug regulatory authority approvals and difficulties caused by the rapid advancements in technology.

Forward-looking Statements

Certain statements in this announcement may contain forward-looking statements regarding the Company business and the therapeutic and commercial potential of its technologies and products in development. Any statement describing the Company's goals, expectations, intentions or beliefs is a forward-looking statement and should be considered an at-risk statement. Such statements are subject to certain risks and uncertainties, particularly those risks or uncertainties inherent in the process of developing technology and in the process of discovering, developing and commercialising drugs that can be proven to be safe and effective for use as human therapeutics, and in the endeavour of building a business around such products and services.

See more here - avecho.com.au

Avecho

Injectable Portfolio Update: Products Differentiated by TPM®

December 2019

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.

Avecho

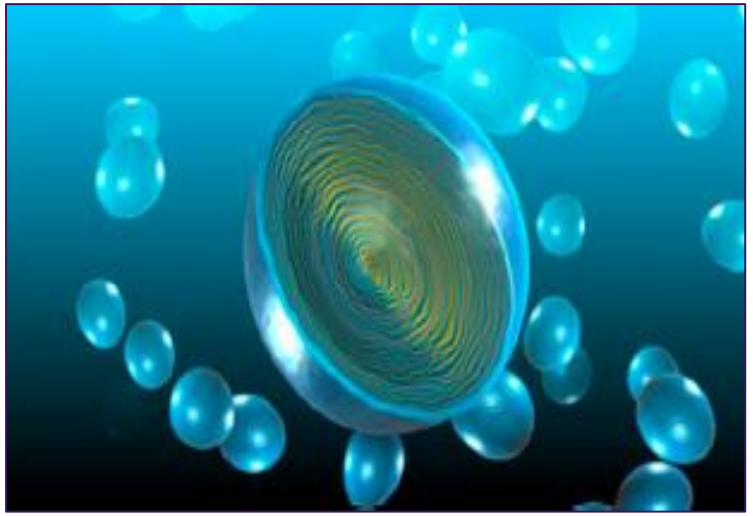
Innovative biopharma company headquartered in Australia

Mission

To become a leading biopharmaceutical company, utilising our TPM® delivery technology to develop innovative therapeutics that address unmet medical needs and enhance patients' quality of life.

TPM® is at the core of Avecho

"…Avecho invented, developed, patented and is the sole global manufacturer and supplier of TPM® …"



TPM® :

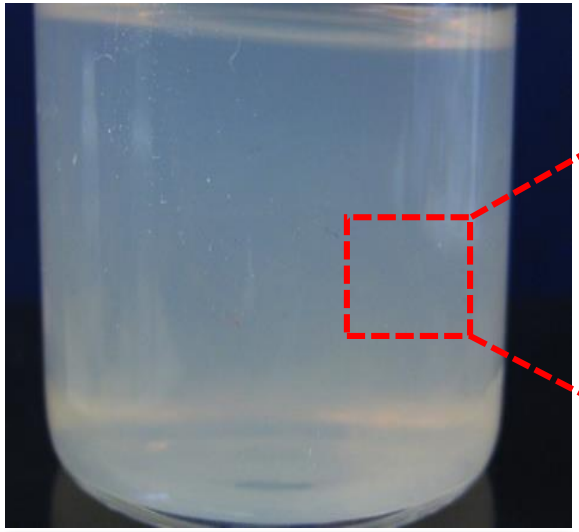
- proprietary combination of 2 forms of phosphorylated Vitamin E (in specific ratio)
- highly flexible technology
- improves drug solubility and stability to enhance injectable products
- enhances transdermal drug delivery and oral bioavailability
- excellent safety profile
- protected by over 100 patents across 13+ families
- Manufactured in Avecho's Melbourne Facility

TPM® is a unique, vitamin based excipient

TPM®:

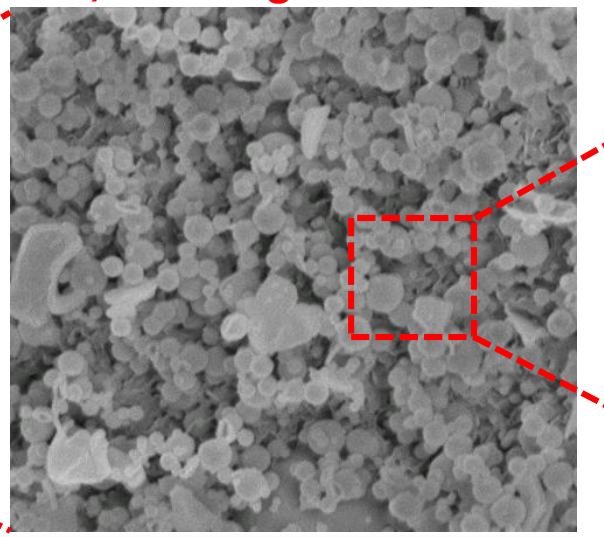
- Proprietary combination of two forms of Vitamin E
- Excellent safety profile
- Highly flexible technology
- Forms microscopic TPM® particles able to encapsulate drug (see below)

x1 magnification



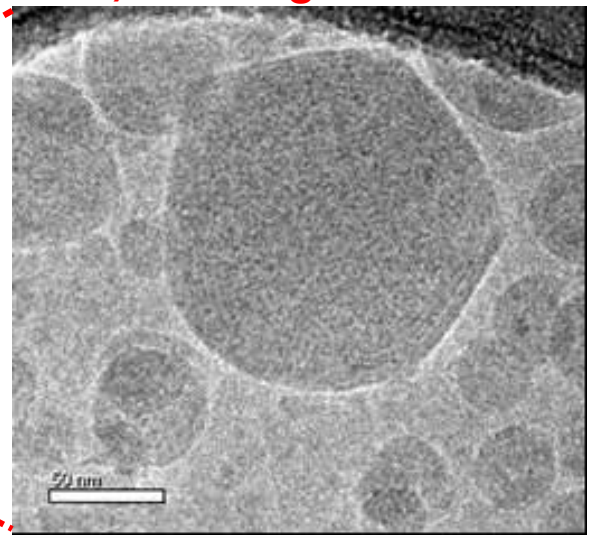
TPM suspension

x25,000 magnification



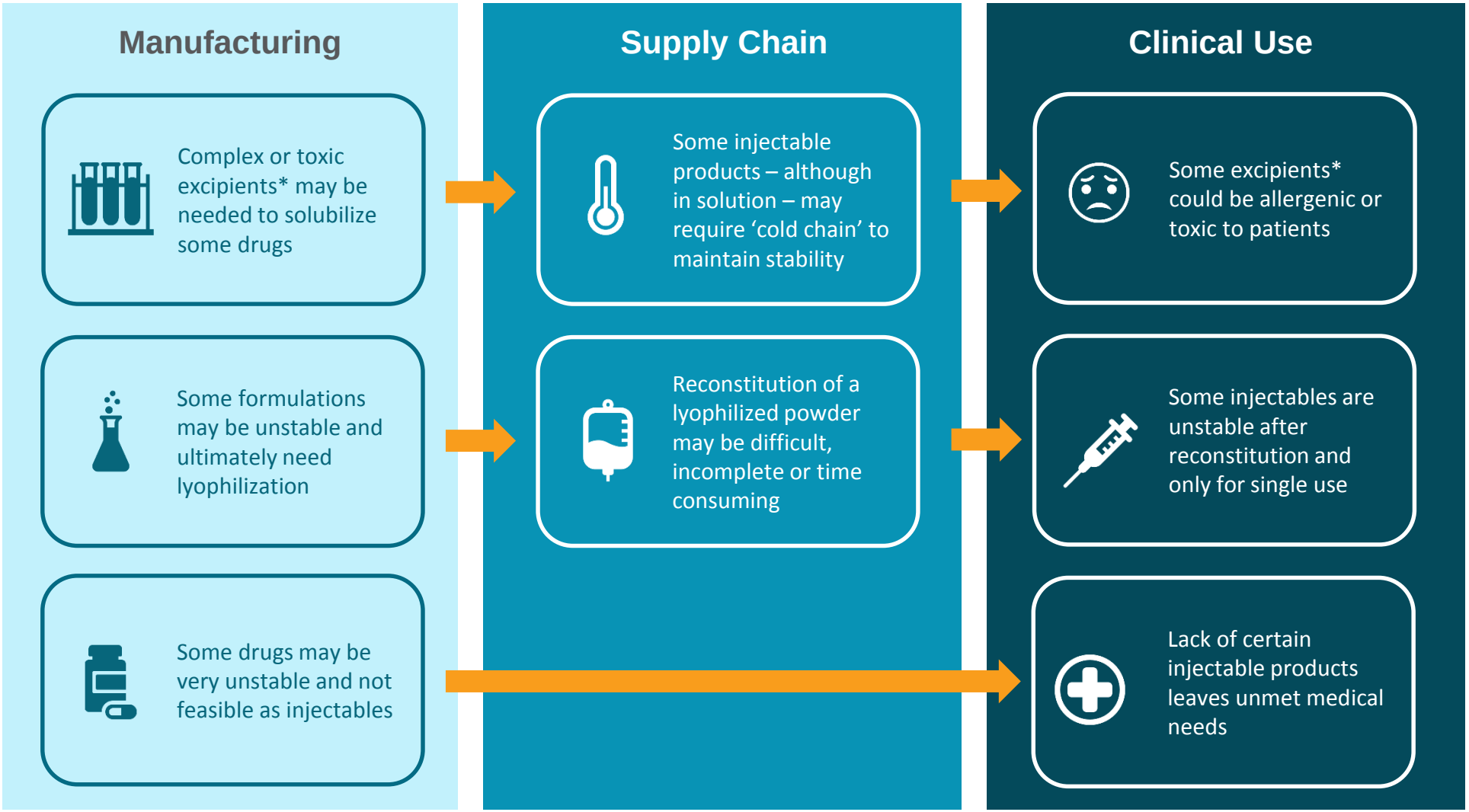
Cryo-SEM

x500,000 magnification



Cryo-TEM

Common challenges for injectable drugs are opportunities for TPM

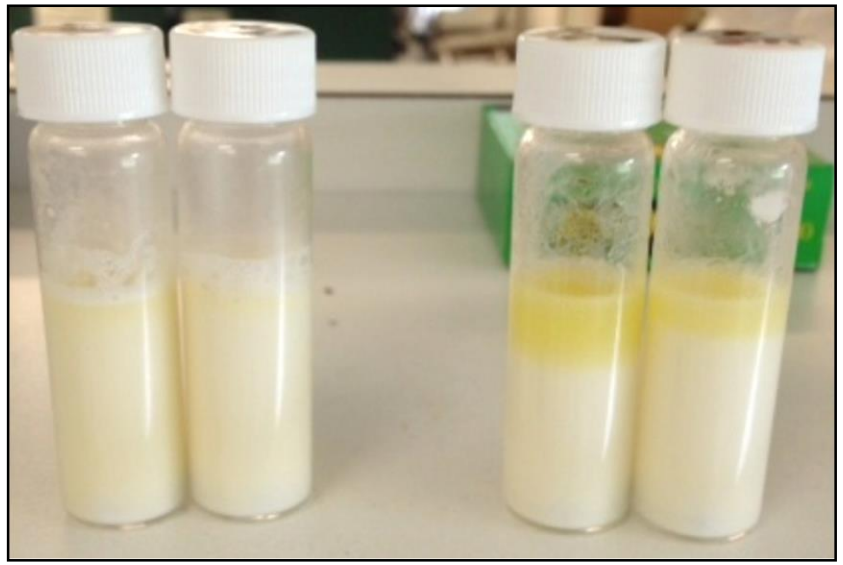


*For example, Cremophor EL is cardiotoxic & nephrotoxic

TPM® increases the solubility of molecules with poor aqueous solubility

- In the absence of detergents or solubilisers, **lipophilic molecules remain undissolved on the surface** (bottom left) **or precipitate at the bottom of aqueous liquids**.
- The addition of **TPM® dissolves the lipophilic/hydrophobic molecules** in aqueous liquids
- This benefit has been demonstrated for **all** lipid soluble drugs examined with TPM

Vitamin D



+ TPM **- TPM**

Increase (times) in drug solubility produced by TPM® in model formulation vehicles. Work conducted independently by Catalent, USA

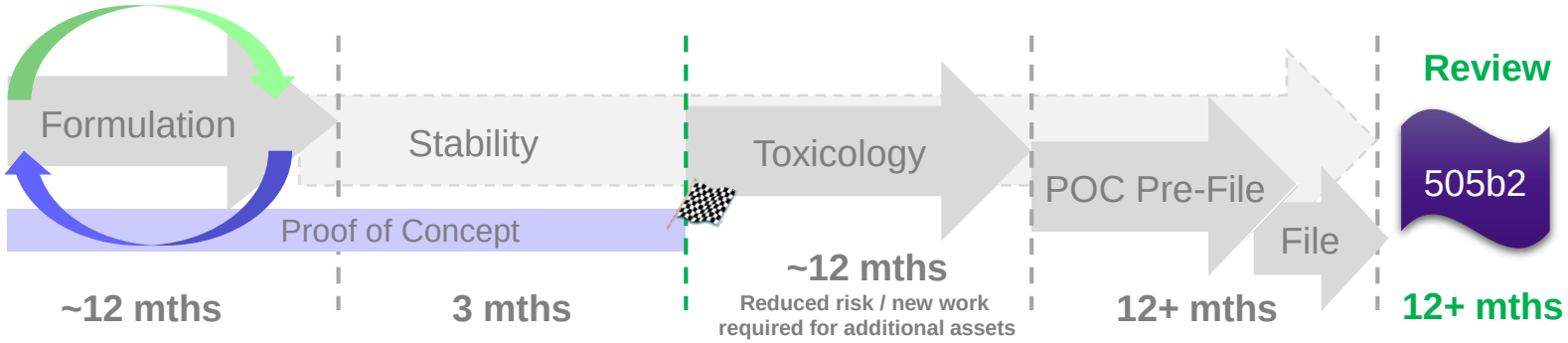
Vehicle	Cyclosporine	Tacrolimus	Vitamin K	Vitamin Mix		
				Vit A	Vit D	Vit E
#1	Increased*	x3.25	x3.65	x214.79	x228.51	x231.9
#2	Increased*	x1.09	x5.42	x930.28	x74.83	x58.34
#3	Increased*	x0.88	x2.72	x54.7	x19.19	x40.63

*Increases in cyclosporine solubility versus control were not quantified

TPM®: Demonstrated benefits for injectable products

- TPM can reduce the reconstitution time of lyophilized peptides
- TPM can increase the stability of reconstituted peptides
- Increase drug solubility for molecules with poor aqueous solubility
- Increase the physical stability of an emulsion
- Transform an opaque emulsion to a transparent microemulsion
- Replace adverse solvents or co-surfactants (Cremaphor, Tween)
- Replace excipients that can cause anaphylaxis (egg or soy phosphatidylcholine)
- Increase drug stability, potentially enabling the formation of liquid formulations (from lyophilized powders or reducing the requirement for cold chain).

“Injectable” assets are fast and profitable



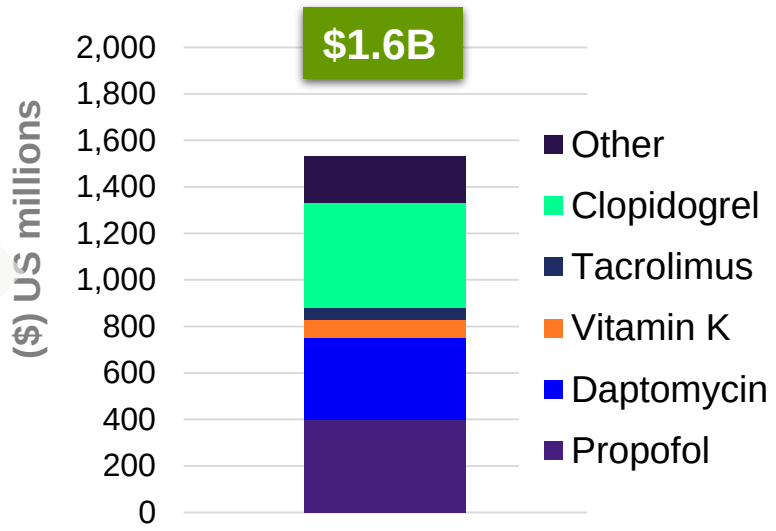
Estimated 2030 US Market for Current TPM/Injectable Pipeline

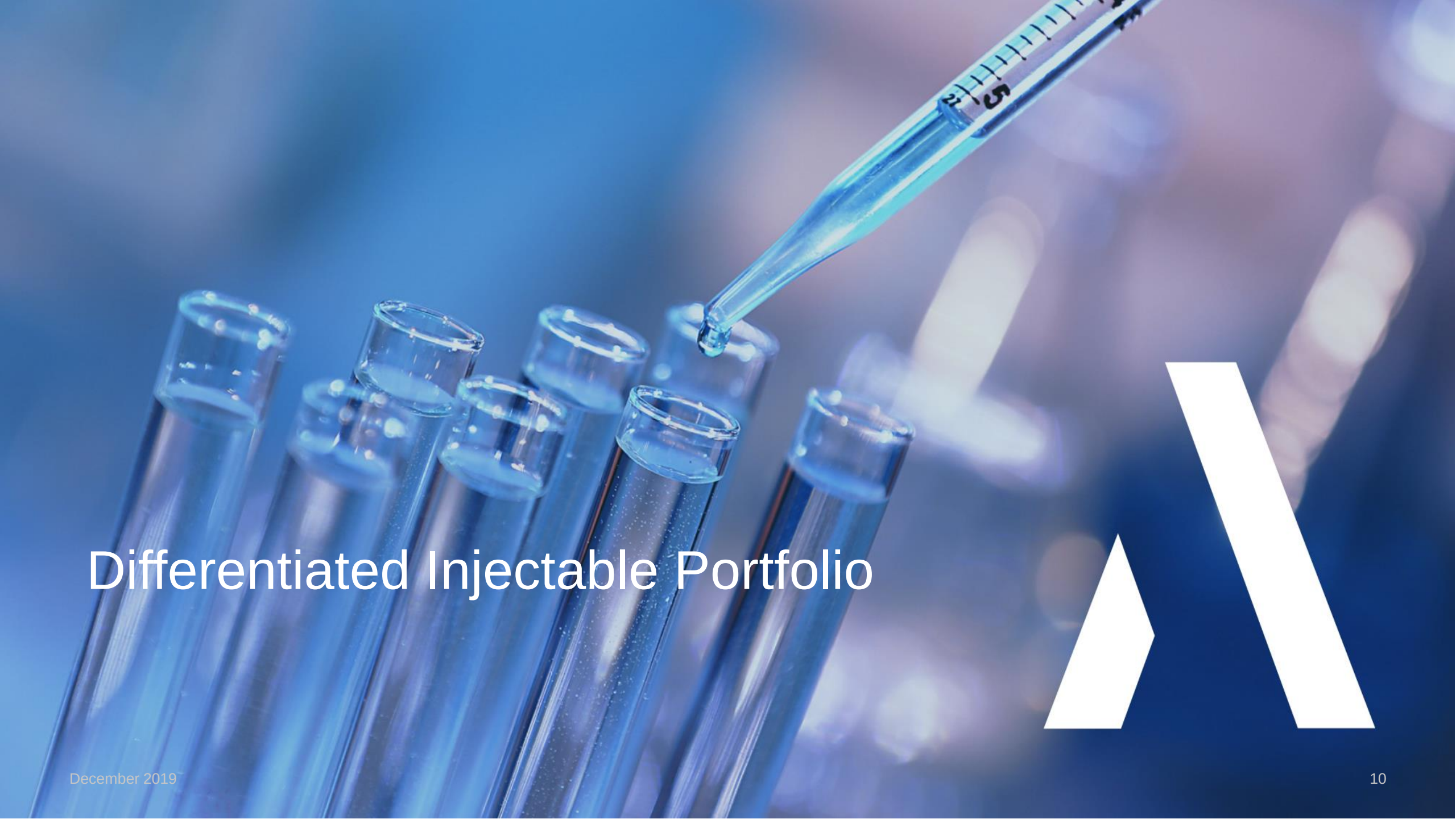
TPM allows:

- Lyophilized to Liquid
- Replacement of toxic excipients
- Improved stability, clarity & reconstitution
- Improved formulation safety & tolerability
- 1st /novel Injectable forms

TPM COGS allows:

- Improved / reformulated 505b2 products at Generic pricing
- Compelling sales margin
- Competitive pricing that capture large volume / market share





Differentiated Injectable Portfolio

TPM® injectable portfolio

- A number of drugs with known injectable formulation issues were identified for reformulation with TPM.
- They were;
  - Daptomycin – Antibiotic used to treat systemic, life threatening infections
  - Propofol – General anaesthetic used during surgery
  - Phytonadione (Vitamin K) – Used for prophylaxis/prevention of blood clotting disorders
  - Tacrolimus – Immunosuppressant used to lower risk of rejection after organ transplant
  - Melphalan – Chemotherapy drug used to treat a variety of cancers
  - Clopidogrel – Oral medication used to prevent/treat heart attack and stroke

TPM®/Daptomycin

- Vancomycin has been the mainstay of MRSA treatment for decades
- Newer products like daptomycin are perceived to be more efficacious; however, treatment today has been limited due to:
  - Higher price of brands
  - Concern that overuse of a new drug will result in more overall resistance and thereby limit the availability of effective medicines to treat severe infections

- Daptomycin went generic in 2016, causing the value of the Cubicin® brand to decline significantly. The generics of Fresenius and Teva became the market leading formulations in 2018, with the total US market worth ~$700M USD.
- The availability of generic daptomycin will increase switching from vancomycin to daptomycin. However, this will be tempered by;
  - The need to prevent further development of bacterial resistance
  - The perceived shortcomings of the daptomycin dosage form (difficulty in reconstitution and short stability after reconstitution).

TPM®/Daptomycin

Problem

- Daptomycin is supplied as a lyophilized powder for reconstitution because it prone to hydrolysis
- The reconstitution process is a laborious (~20min), making it difficult to administer
- Daptomycin only stable for 12 hours at RT once reconstituted.
- The short time frame of stability and insufficient vial size lead to significant product wastage.

\+ TPM®

TPM®/Daptomycin

= Solution

- Daptomycin protected from hydrolysis
- Increased daptomycin solubility, allowing reconstitution in < 5 minutes to significantly increase workflow efficiency in the hospital
- Daptomycin shelf-life stability increased to 24 hours at RT, and 72 hours in fridge. Longer stability leading to reduction of waste of significant market value.
- Longer stability also enables larger, multi-use vials and commercial supply chain advantage.
- Key differentiation over generics

Increased stability and solubility address hospital pharmacy unmet needs

Longer stability is of significant value to the market

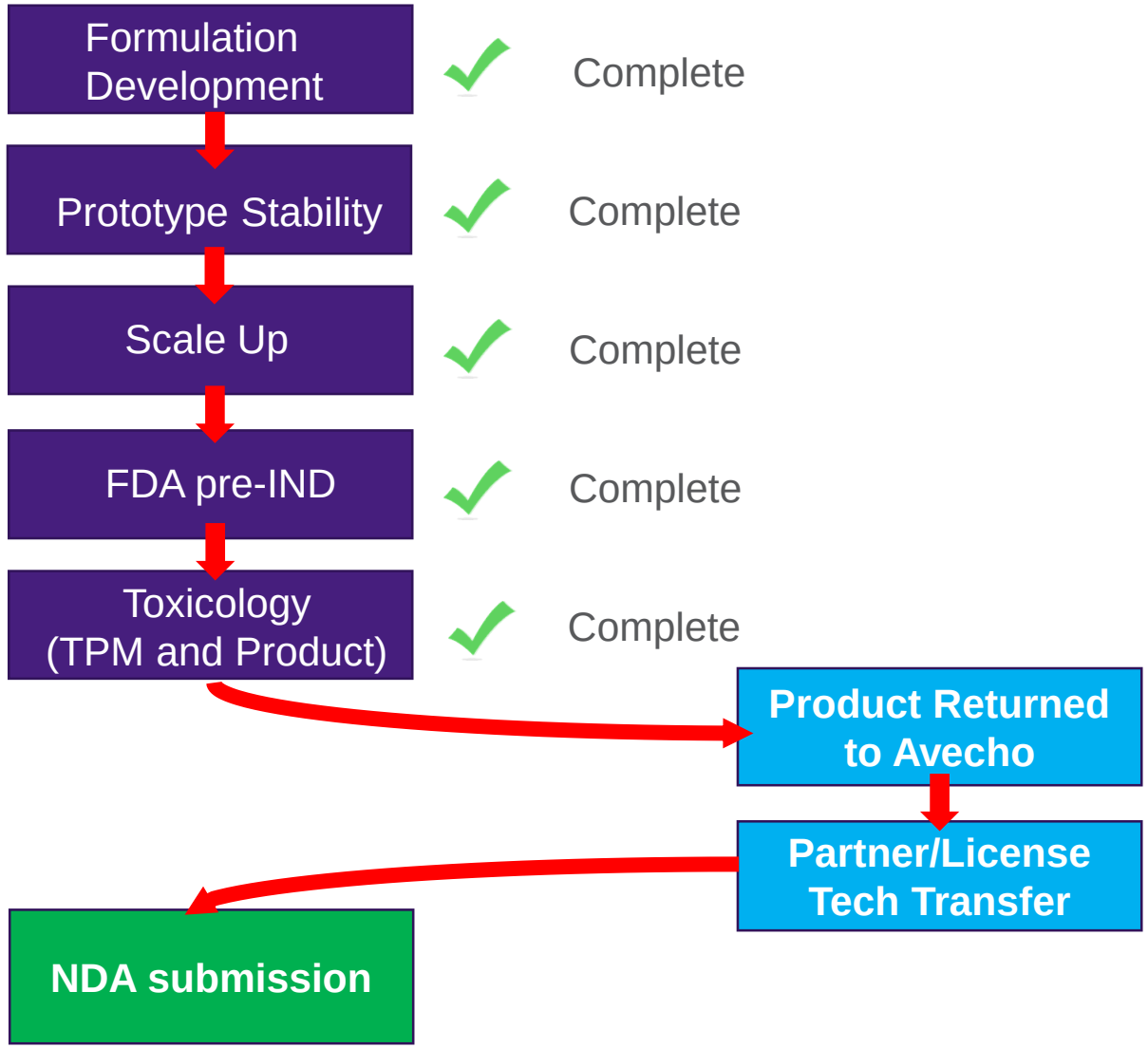
- Hospital pharmacies identify daptomycin waste as a primary concern
  - Waste due to **short time frame of stability**
    - Hospitals try to reduce waste by preparing Cubicin® on an as-need basis, only 2-3 hours before the scheduled administration time
    - However, when an order is cancelled, e.g. patient is discharged, the short stability usually ensures the product is discarded before another appropriate patient presents.
  - Waste due to **insufficient vial size**
    - Some patients require more than 500mg; pharmacists must open a second vial if patients require more, and the excess is thrown out if it cannot be used by the end of the day due to Cubicin®'s short stability

Increased solubility will help improve pharmacy workflow

- Cubicin®'s preparation today takes time and is a hassle

Daptomycin TPM® offers value to the hospital pharmacy in **increased stability and workflow efficiency.** Consequently**,** it may be able to garner a price premium over plain generic daptomycin

TPM®/Daptomycin is nearly NDA ready



- Majority of development is complete
  - Product significantly de-risked
- The FDA has provided comment on the remaining work required to submit an NDA
  - Toxicology program is complete
  - No clinical trials expected to be required
- Avecho plans to commercialise the product
  - Consequently, Avecho is looking to partner with a suitable pharmaceutical partner able to manufacture/distribute.
  - The formulation must be tech transferred to their manufacturing facility.
  - The NDA could be submitted once that work is completed

TPM®/Propofol

Problem

- Propofol is an insoluble oil
- Consequently, the formulation requires soybean oil and lecithin which have been linked to anaphylaxis.
- The oil and phospholipids can promote microbial growth, which has been linked to sepsis and death – resulting in recalls and shortages.
- The formulation is opaque (not transparent) limiting QC / confidence.
- Pain upon injection that may be caused by large particles

\+ TPM®

TPM®/Propofol

With TPM®

Without TPM®

=

Solution

- TPM creates a transparent and thermodynamically stable microemulsion
- No egg or soy based excipients, no risk of anaphylaxis, and reduced risk for bacterial growth
- Clear formulation allows QC and confidence during infusion / mixture – less chance of product recall
- Simple manufacture method; COGS projected to be cheaper than standard propofol emulsion
- TBD: clear formulation / smaller particles reduce pain upon injection?

A clear propofol microemulsion has advantages for physicians and manufacturers

Even as a generic product, propofol is about an $800 million global market.

- A clear, transparent product able to be visually inspected would be preferred by physicians.
- A formulation that is free of oils and lipids would be less susceptible to QC, contamination and recall problems
- We expect that TPM®/Propofol could grow the overall propofol market, which has suffered from manufacturing issues and resulting product shortages.

Fresenius dominates the US marketplace, mostly due to a tight manufacturing and QC process consistent supply to the market

- TPM® would significantly reduce the risk and expense of the supply chain for propofol and provide significant value to another manufacturer
- Initial estimates also suggest that the TPM®/propofol formulation would have cheaper COGs than the commercial, opaque emulsion.

Despite being a relatively old generic product with little innovation, the propofol market remains strong**.** An oil free, clear propofol would have clear advantages all the way from manufacturing to patient administration. These advantages would be expected to support a price premium over generic propofol

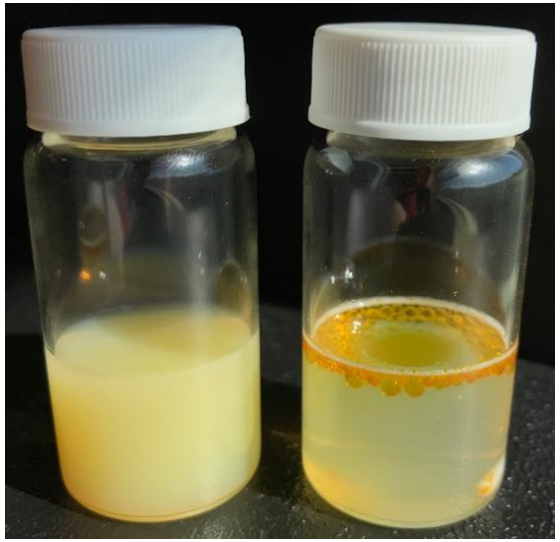
TPM®/Vitamin K

Problem

- Vitamin K is an insoluble oil that requires formulation with an emulsifying agent
- Research has shown that adverse reactions to the Vitamin K injection may be caused by the excipients (Cremaphor or polysorbate) used to emulsify the molecule
- Because of risks associates with the injectable formulation, many mothers choose oral Vitamin K for newborns, which has been shown to be less efficacious
- If the adverse excipients (Cremaphor/Tween) could be replaced with Vitamin E, it may provide for a safer injectable formulation of Vitamin K

\+ TPM®

TPM®/Vitamin K



With TPM® Without TPM®

= Solution

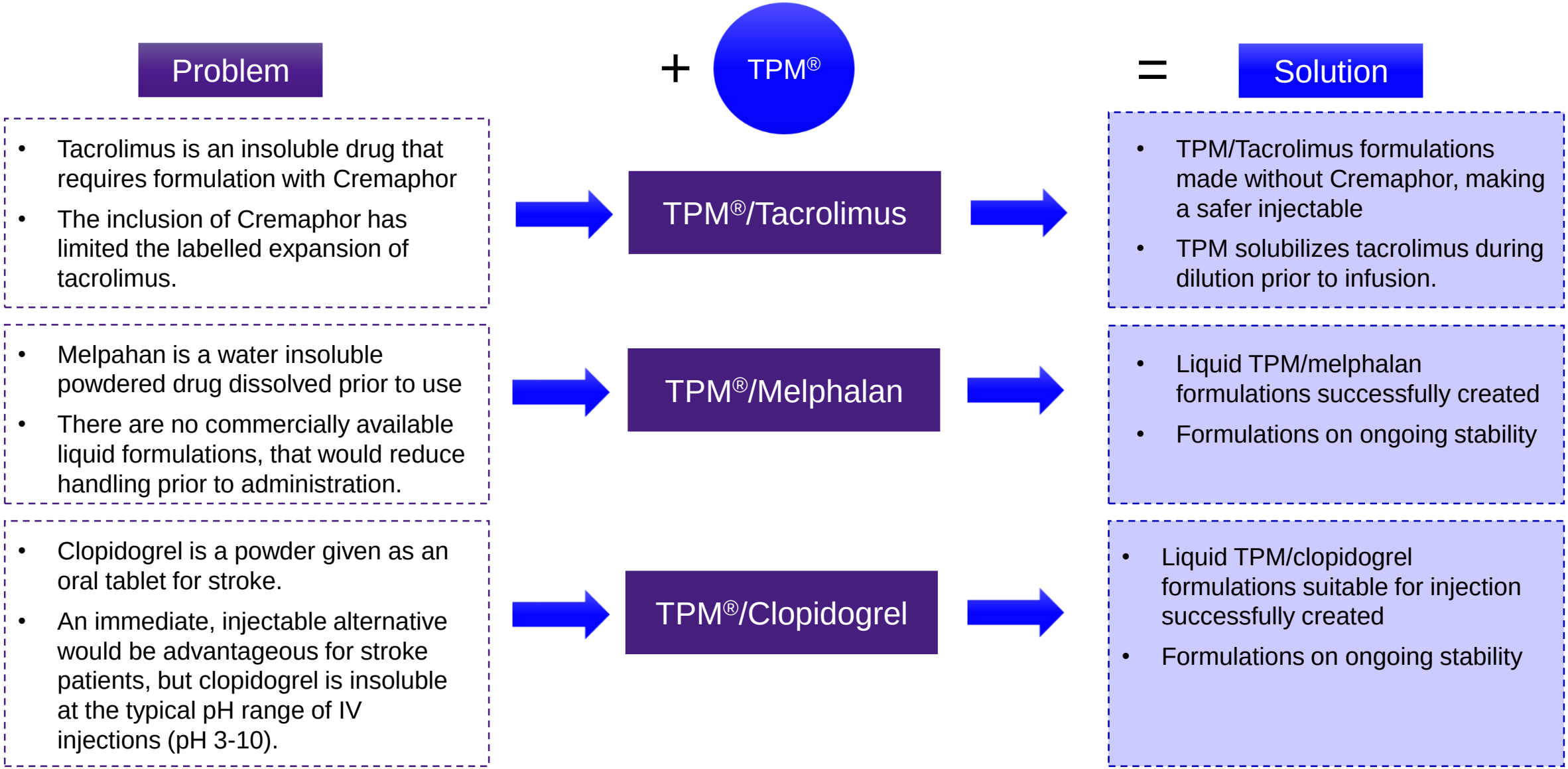
- TPM dissolves the Vitamin K in a stable, colloidal vesicle system
- Vitamin K formulations can be made without Cremaphor, Tween or Lecithin. Solubilisers known to cause adverse reactions can be replaced by Vitamin E.
- There are no known allergens in the product, and no anticipated safety concerns.
- A safer Vitamin K injection may allow resumption of routine Vitamin K injections, with lesser associated risks of adverse reactions

Replacing Cremaphor and Tween with Vitamin E makes for a safer Vitamin K injectable for newborns

- Serious adverse reactions to the Vitamin K injection may be caused, or made worse, by excipients used to solubilise the molecule (Cremaphor or Tween).
- Vitamin K injections increase survival rates of newborns, but because of the risks associated with the injection, many physicians/mothers choose oral Vitamin K for newborns. The oral dosage form has been shown to be less efficacious.
- New Vitamin K formulations have been developed that replace Cremaphor/Tween-80 with TPM, a form of Vitamin E**.**
- **These formulations do not contain any known allergens or adverse excipients, and would allow routine vitamin K administration to newborns as a cost effective intervention to reduce preventable neonatal deaths.**
  - The removal of Cremaphor and Tween may also allow IV injection for other Vit K indications, which has previously been the subject of a labeled box warning due to allergic reactions.

It is anticipated this safer formulation would replace the other generics on market, and become the preferred Vitamin K injection for neonates, in addition to some of the other indications.

Further TPM® injectable products



Current status of injectable portfolio available to partner/license

	Reformulation Aims	Status
Daptomycin	Decrease reconstitution time and increase reconstitution shelf-life	Formulation completed by Mylan. Toxicology complete. Nearly NDA ready.
Propofol	Make a clear injectable liquid while removing potential allergens (soy bean oil or egg lecithin)	Ongoing toxicology program. Vehicle safe for induction/short term infusion
Vitamin K	*Reformulate to replace Cremophor/Tween with TPM*	Stability ongoing. Formulation stable for 18 months at RT. 2 year point in Jan 2020.
Clopidogrel	*Making solid oral formulation into an injectable liquid*	Stability ongoing. Formulation stable for 18 months at RT. 2 year point in May 2020.
Melphalan	*Making powdered formulation into a liquid*	Stability ongoing. Stable 18 months 2-8^{o}C. 2 year point in May 2020.
Tacrolimus	*Replace Cremophor*	Stability ongoing. Formulation stable for 12 months at RT. 2 year point in Dec 20.

Commercial advantages of injectable products reformulated with TPM®

- **Product differentiation/superiority versus generics**
  - Removing adverse excipients makes for a safer injectable
  - Physician preferred presentations
  - Increased efficiencies in hospital workflow
  - Potentially cheaper COGS

- **Patent protection**
  - The inclusion of TPM® enables strong patent protection

- **Premium pricing versus generics**
  - The differentiation provided by TPM® will often support increased pricing versus generics

Experienced Management & Board with strong track record of success

Dr Greg Collier, Executive Chairman

- 20+ yrs experience
- Previous: CEO of ChemGenex (sold to Cephalon for $200M+)
- 150 peer reviewed publications, 33 patents, Roche Award for Excellence

Melanie Leydin, CFO & Company Secretary

- 23 years experience in accounting.
- Member of the Institute of Chartered Accountants.
- A registered Company Auditor.
- Director/founder Leydin Freyer

Dr Ross Murdoch, Non-Executive Director

- 25+ yrs experience; joined Avecho in 2015 as CEO
- Currently CEO of Tasman Alkaloids
- Previous: SVP Shire Pharmaceuticals, President & COO Prana Biotechnology

Dr Paul Gavin, CSO

- 17+ yrs with Avecho; an inventor of the TPM® platform technology
- Responsible for all Research & Development at Avecho

David Segal, Non-Executive Director

- 30+ yrs experience as a stockbroker
- Shareholder of Avecho since 1999 (when known as Vital Capital)
- Previous: Investor Relations manager of Avecho

Dr Roksan Libinaki, GM Animal Health & Production

- 17+ yrs with Avecho, managing R&D programs focused on improving animal health
- Responsible for the manufacture of TPM

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