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November 2018

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# About Recce Pharmaceuticals Ltd

- ▶ Founded in 2008
- ▶ Publicly listed on ASX 2016 (ASX:RCE)
- ▶ Whole new class of antibiotic that kills bacteria including its superbug form even with continued use
- ▶ RECCE<sup>®</sup> 327 – broad spectrum antibiotic; lead indication is for sepsis - #1 most expensive condition
- ▶ Qualified Infectious Disease Product (QIDP) designation  
RECCE<sup>®</sup> 327 labelled under GAIN Act for:
  - 10 years market exclusivity (post approval)
  - Fast track (life of regulatory process)
- ▶ Patented manufacturing producing to Phase I & II volumes



*Recce is a drug discovery and development business, commercialising a new class of synthetic antibiotics to address the global health challenge of antibiotic resistant superbugs.*

# Recce Pharmaceuticals Ltd - Capital structure

## Major shareholders 30 September 2018

1. G. & O. Melrose*	35.0%
2. Foord Asset Management	4.6%
3. J. Graham*	4.0%
4. M. Dilizia*	3.2%
5. State One Equities	2.8%

## ASX:RCE 6 months



\* Held by Executive Directors

## Snapshot

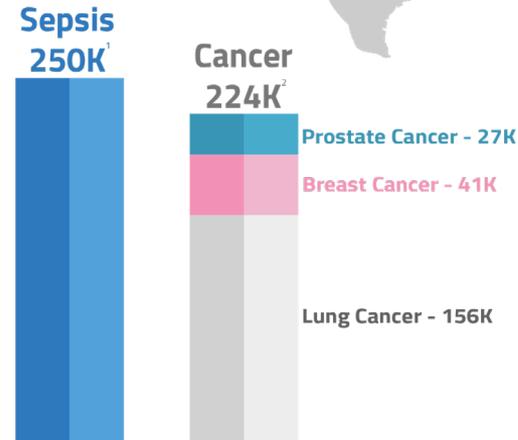
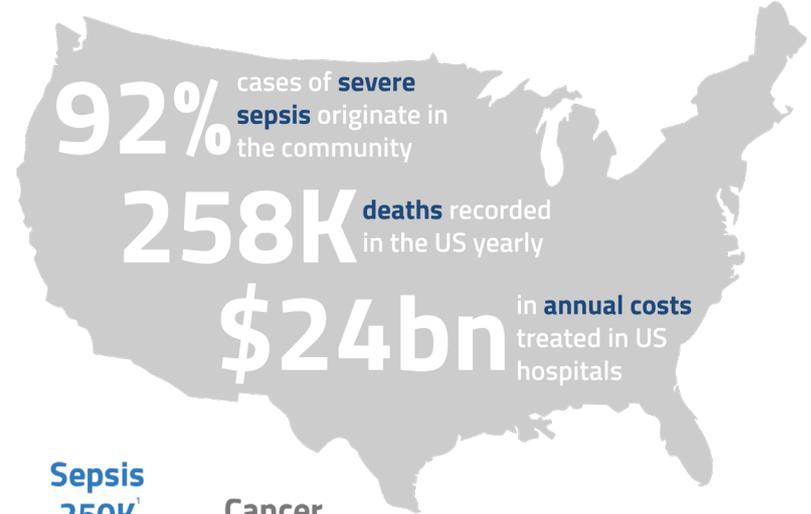
ASX code	<b>RCE</b>
Shares on issue	<b>89.34 million</b>
Share price	<b>AUD 17.5 cents</b>
Market Cap (approx.)	<b>AUD \$15.6 million</b>
Cash and deposits 30 June 2018	<b>AUD \$0.68 million</b>
Trading range 52 week	<b>AUD 14-26.0 cents</b>
Average daily volume 3 months	<b>31.9K</b>

# Tackling superbugs – RECCE® 327 (video)



# Sepsis – it's a big problem!

- ▶ Sepsis is a life threatening inflammatory response to infection that has spread in the body
- ▶ Leading cause of death in intensive care units and top 10 cause of mortality worldwide
- ▶ Two per cent of hospitalisations are for sepsis but they make up 17% of in hospital deaths
- ▶ Sepsis kills more people in the US than prostate, breast and lung cancer combined
- ▶ Most expensive condition to treat - double the average cost per stay across all other conditions
- ▶ Currently no drug therapies specifically for the treatment of sepsis
- ▶ Desperate and unmet medical need for new safe and efficacious products



# Natural antibiotics vs synthetic antibiotics

- ▶ Overuse of antibiotics has led to antibiotic resistant bacteria in humans and animals (superbugs)
- ▶ Antibiotic resistance is widely acknowledged as an urgent global health issue
- ▶ Commercial antibiotics are naturally derived – superbugs have been forming for millennia – and will continue to do so!
- ▶ RECCE® 327 is a new class of broad-spectrum antibiotic
  - Entirely man-made and designed with purpose – not reliant on what's found in nature.
  - **Unique mechanism of action** – many 'Active-sites', as opposed to the traditional (natural) antibiotics 'few'.
  - Universal mechanism of action - detailed experimentation demonstrates it does not succumb to superbugs.



Pre-formed  
natural superbugs

Contain natural antibiotics



**NO** Pre-formed  
natural superbugs

Synthetic antibiotics

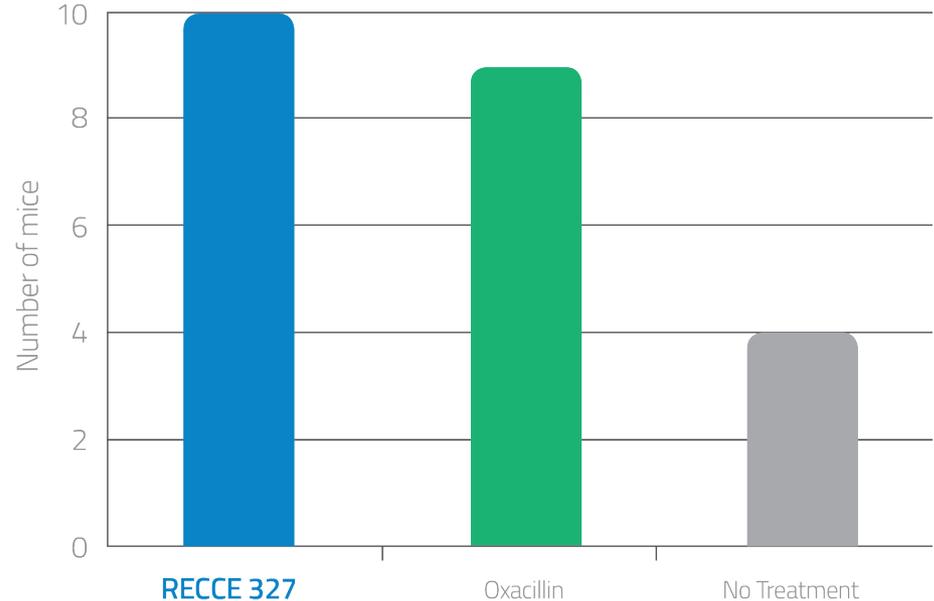
# RECCE<sup>®</sup> Antibiotics – Curative study\*

- ▶ Three groups of 10 mice were each infected with MRSA (*S. aureus* superbug)
- ▶ All ten mice treated with RECCE<sup>®</sup> antibiotic survived
- ▶ Nine mice treated with current antibiotic (Oxacillin) survived
- ▶ Four mice that had no treatment at all, survived

Note: Oxacillin was chosen for its known activity against MRSA. It is however a ‘narrow-spectrum’ antibiotic. In a clinical context, where diagnostics cannot immediately determine bacterial type, use in combatting any number of other bacteria, may likely see a less favorable patient outcome...

RECCE<sup>®</sup> 327, with its proven ‘broad-spectrum’ activity, has shown strength against a range of bacteria including superbug forms, delivering rapid kill of deadly germs.

Number of mice that survived  
Sepsis from *S. aureus* (superbug)

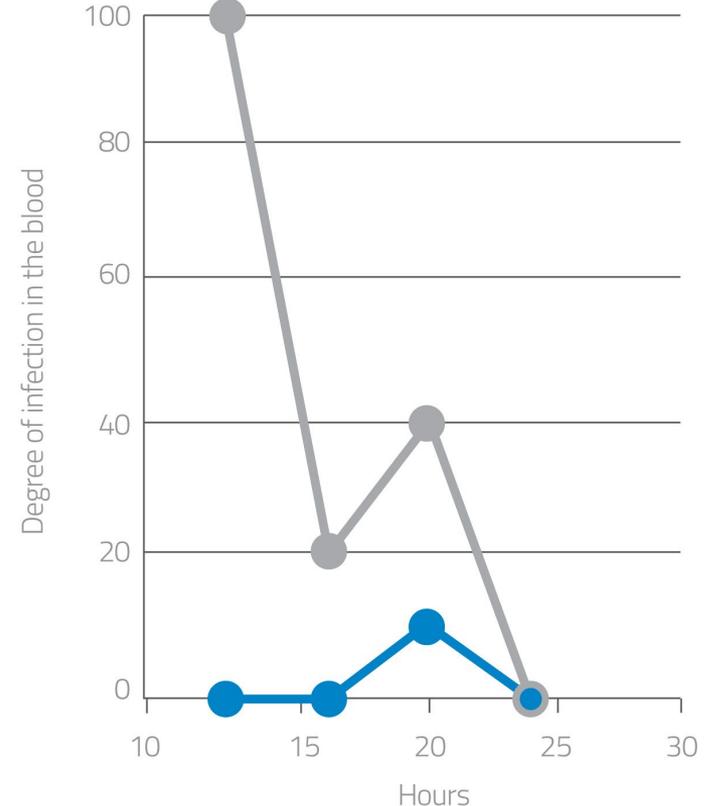


# RECCE® Antibiotics – Preventative study\*

## Controlled study with two groups of mice:

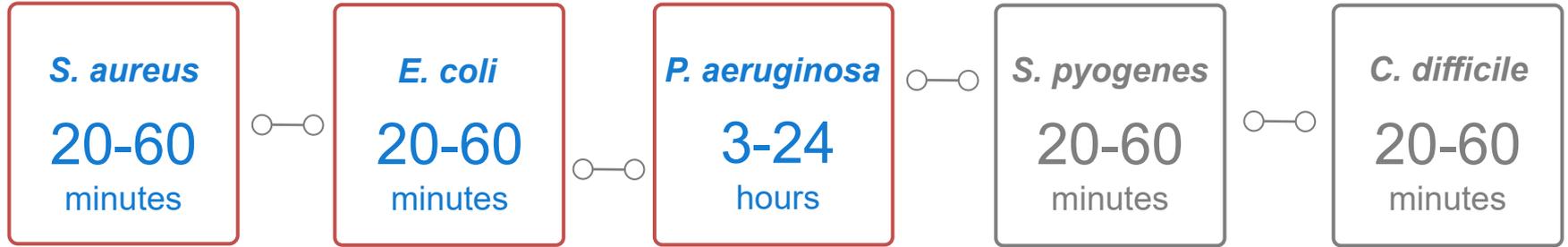
- ▶ **Blue** group represent mice with RECCE® 327 already flowing through blood stream
- ▶ **Grey** group represent mice with no treatment
- ▶ At 0 hours both groups were introduced with significant *S. pyogenes* bacterial burden to the blood stream
- ▶ Due to RECCE® 327 already present in a preventative role, introduction of bacteria to the **blue** group **DID NOT** lead to established infection
- ▶ Results were monitored at 12<sup>th</sup> hour (per industry standard) to allow bacterial infection to develop in host
- ▶ After the 12<sup>th</sup> hour, *S. pyogenes* appears to be clearing naturally from the blood – **WRONG**
  - Bacteria in grey group rapidly colonising in the kidneys – commonly resulting in catastrophic organ failure
  - **NOT** in RECCE's case. Bacteria in blood rapidly killed and unable to establish infection in kidneys

Sepsis in mice from  
*Streptococcus pyogenes*

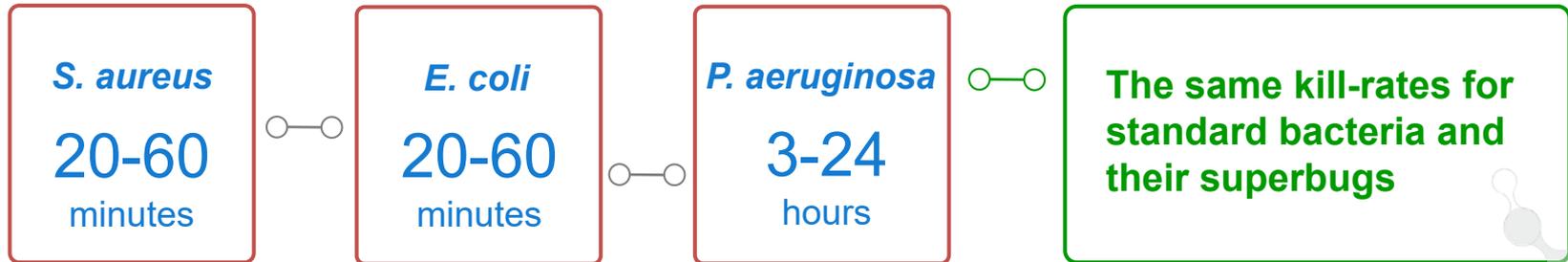


# RECCE<sup>®</sup> antibiotics kill at practical speeds

## Rates of kill of standard bacteria

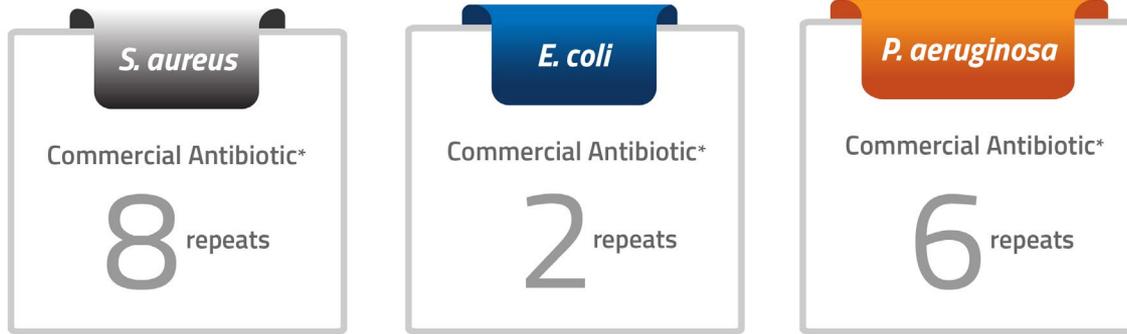


## Rates of kill of Superbugs



# RECCE<sup>®</sup> antibiotics do not Fail<sup>1</sup>

Number of repetitive uses before displaying loss of antibiotic activity

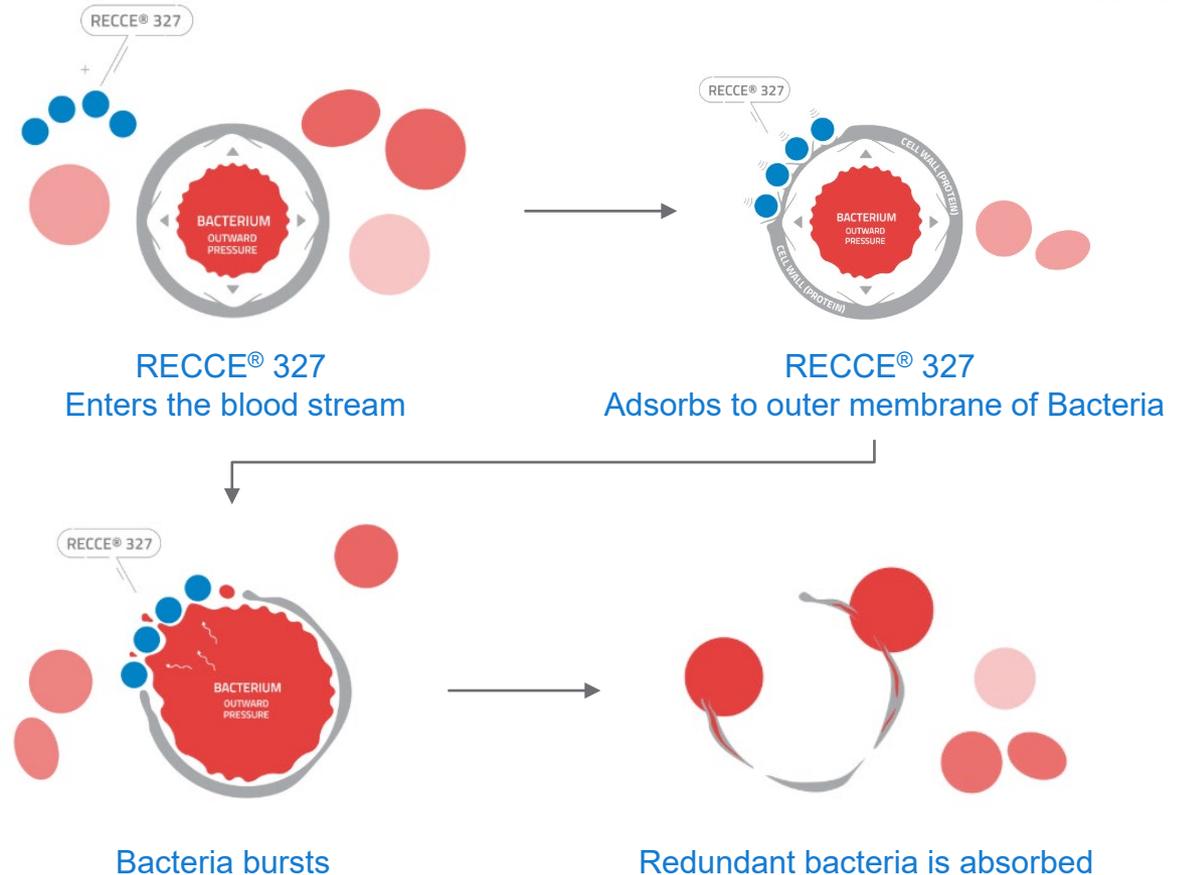


**RECCE<sup>®</sup> Antibiotic** more than **25** repeats

<sup>1</sup>After repetitive use, the commercial antibiotic loses activity; >25 repeats **RECCE<sup>®</sup> antibiotic DOES NOT**

# RECCE® 327 – how it works (in more detail)

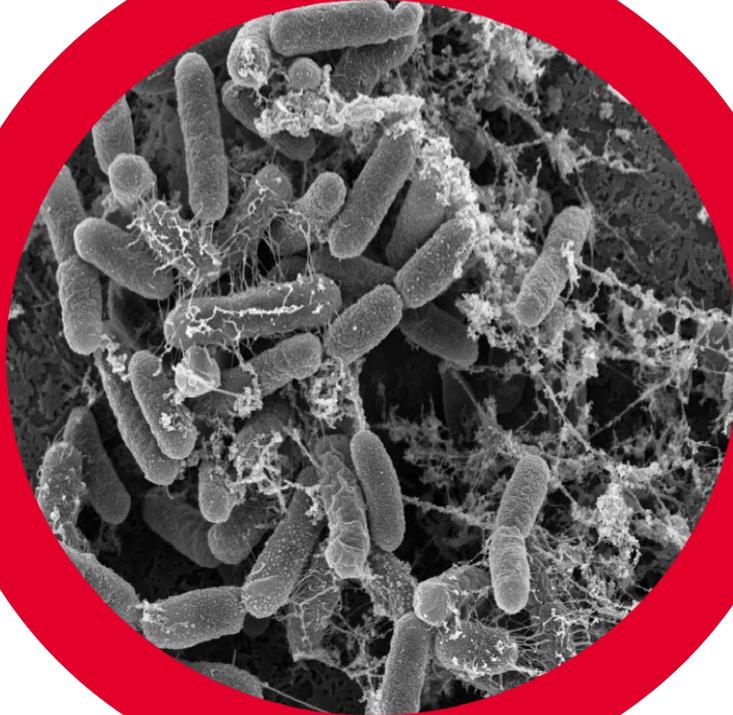
- ▶ RECCE® antibiotics, attracted by protein in a bacteria's outer membrane, non-specifically attach through hydrophobic interaction
- ▶ Weakening the outer cell wall, internal pressure causes the bacteria to burst and lose viability
- ▶ Outer protein can mutate as much as it likes (superbug) - RECCE® antibiotic will still kill it!



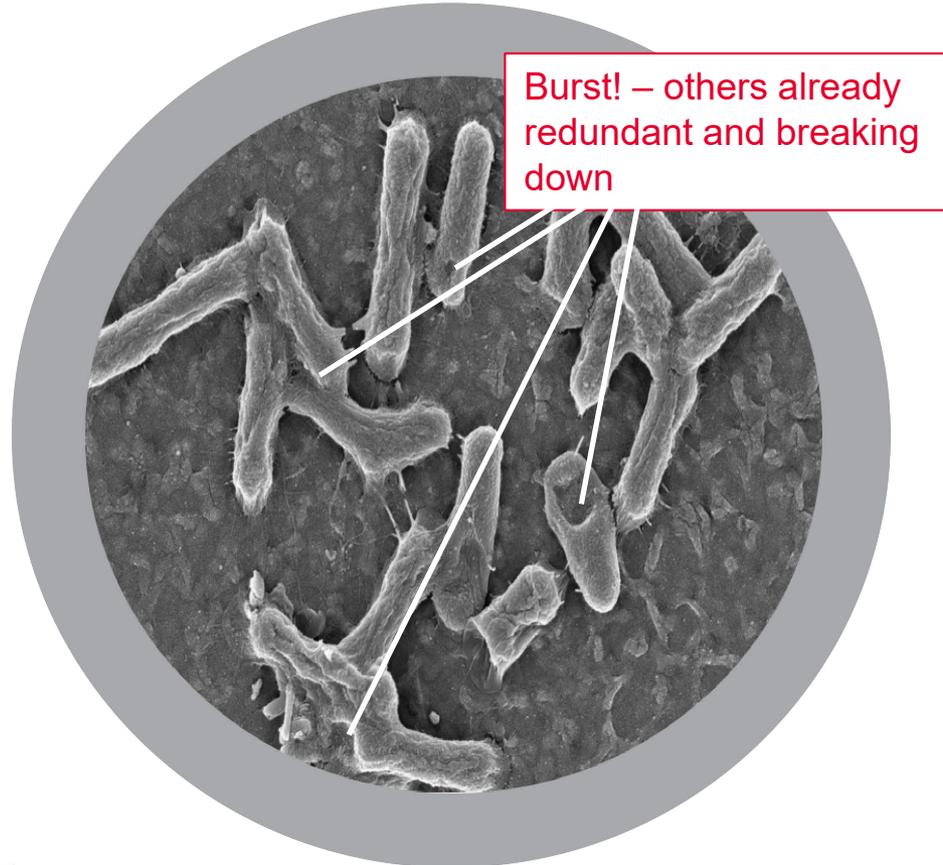
# RECCE<sup>®</sup> 327 mechanism of action in practice

00:00 minutes

Before application  
of RECCE<sup>®</sup> 327,  
the *E.coli* bacteria  
cells are healthy,  
smooth and intact



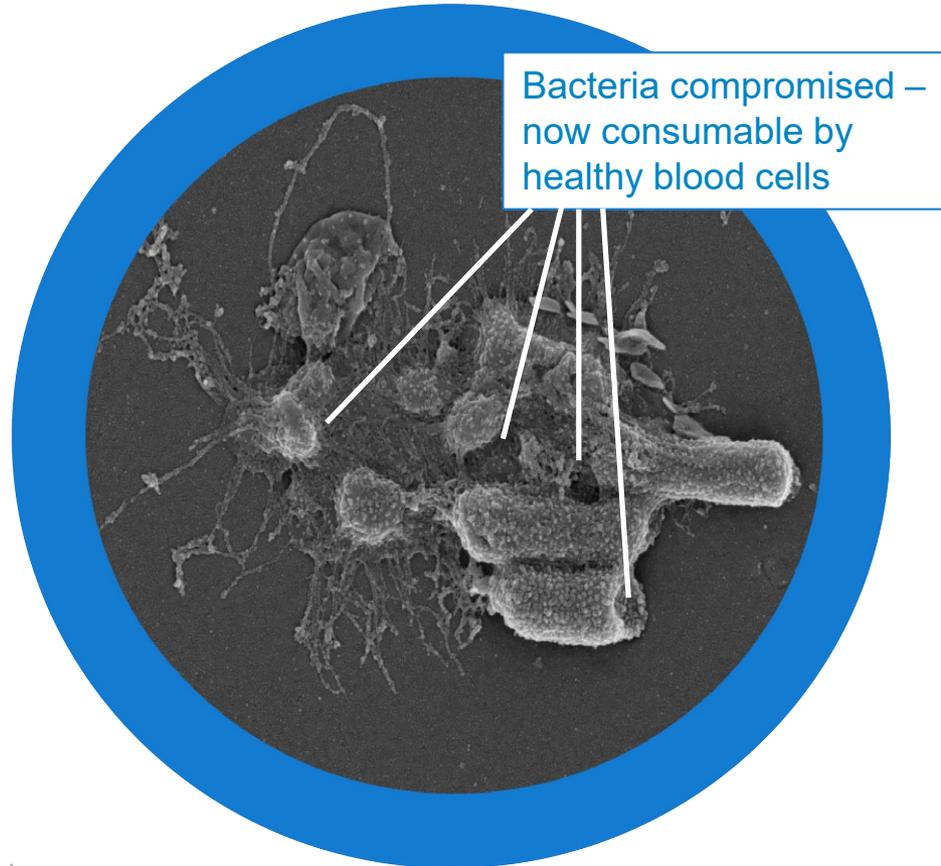
# RECCE<sup>®</sup> 327 mechanism of action in practice



20 minutes

After application of RECCE<sup>®</sup> 327, the *E.coli* bacteria cell membrane begins to weaken and is disrupted

# RECCE<sup>®</sup> 327 mechanism of action in practice



180 minutes

*E. coli* bacteria  
cells (10e6 cfu/ml)  
having their outer  
membrane weakened  
– and bursting from  
treatment with  
RECCE<sup>®</sup> 327 (1000  
ppm)

# RECCE<sup>®</sup> 327 – Safety and Efficacy (detail)

## Efficacy

- Performs as a broad spectrum antibiotic
- Acts against bacteria in both normal and mutated superbug forms
- Multiple tests demonstrate efficacy against Gram-positive and Gram-negative *S.aureus* and *E.coli* including superbug forms
- Rate and MIC/MKC data demonstrates potency and broad spectrum activity against a range of bacteria
- Contains a patented polymeric structure, intentionally designed to overcome the traditional challenges of bacterial mutation/resistance
- *In-vivo* (mice) study against influenza virus

## Safety

- Multiple studies of toxicity in small and large animals
- Multiple tests of mutagenicity (cancer) are clear
- Numerous studies to date indicate the safety of RECCE<sup>®</sup> 327
- Is suited to administration against sepsis by intra-venous drip
- Indicates a safe therapeutic dosing window



# What is Qualified Infectious Disease Product?

- ▶ Legal status awarded under *US Generating Antibiotic Incentives Now (GAIN) Act*
- ▶ Labeled for **fast track designation** – speed the FDA’s review process
- ▶ **10 years market exclusivity**, starting from the date of New Drug Application approval if RECCE® 327 completes the necessary clinical trials and is approved by the FDA
- ▶ QIDP designated drugs to treat serious or life-threatening conditions and fill an unmet medical need, are labeled for expedited review in order to facilitate their development

Qualified Infectious Disease Product (QIDP) designation is awarded if FDA considers the drug to treat “*serious or life-threatening infections, including those caused by an antibacterial or antifungal resistant pathogen.*”



# Patents and trademarks

Patent portfolio covers all key geographies, manufacturing and modes of use

Filed	Patent Family 1 <u>Granted</u>	Expiry	Patent Family 2/3	Expiry	Trademarks registered
Australia	✓	2028	✓	2035	✓
USA	✓	2029	Pending	2035	✓
Europe	✓	2028	Pending	2035	✓
Germany	✓	2028	Pending	2035	-
Spain	✓	2028	Pending	2035	-
France	✓	2029	Pending	2035	-
United Kingdom	✓	2028	Pending	2035	-
Italy	✓	2028	Pending	2035	-
Sweden	✓	2028	Pending	2035	-
Japan	✓	2028	Pending	2035	✓
China	✓	2028	Pending	2035	✓

## Patent Family 1 – granted

Unique and highly economical manufacturing process

## Patent Family 2 – pending

Applications (Multi-drug delivery)

## Patent Family 3 – pending

Anti-viral uses

## Trademarks

RECCE® for use on pharmaceutical products and services

# Manufacturing and production

- ▶ Wholly owned automated manufacturing facility in Sydney's Macquarie Park
- ▶ Raw materials plentiful and CHEAP - few \$/kilogram
- ▶ Automated manufacture process taking around 1¼ hours
- ▶ No expensive waste – 99.9% product yield
- ▶ Currently producing in volumes to support planned Phase I and Phase II clinical trials
- ▶ Facility built to pharmaceutical specification



Principal Engineer Arthur Kollaras & Executive Chairman/Chief Research Officer Dr Graham Melrose assess finished product

# Board and management structure

## Dr Graham Melrose – President & CRO

*BSc (Hons), PhD (UWA), MBA (Macq), FRACI, C Chem, FAICD*

Founder and inventor. Former Executive Director and Chief Research at Johnson & Johnson (Aust) Pty Ltd in Sydney, with global responsibilities, particularly in Asia-Pacific

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## Michele Dilizia – Vice President

*BSc (Med Sci), Grad Dip Bus (Mkting), BA (Journ), GAICD, MASM*

Co-inventor and qualified medical scientist; specialisation in medical microbiology and regulatory affairs

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## James Graham – Vice President

*BCom (Entrepreneurship), GAICD*

Extensive experience in marketing, business development and commercialisation of early stage technologies with global potential

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## Dr John Prendergast – Non-Executive Vice President

*BSc (Hons), MSc (UNSW), PhD (UNSW), CSS (HU)*

US based, current Chairman and Co-founder of Palatin Technologies, Inc. (NYSE: PTN) and Lead Director of Heat Biologics, Inc. (NASDAQ: HTBX) – extensive experience in the international commercialisation of pharmaceutical technologies

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## Alistair McKeough – Company Secretary (Outsourced - Whittens & McKeough)

Alistair is a qualified lawyer and Principal/Managing Director of McKeough & Whittens, Alistair has broad experience as a commercial litigator and Company Secretary to ASX Listed companies

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## Justin Reynolds – CFO (Outsourced - Pitcher Partners Sydney)

Justin is a qualified accountant and Partner of Pitcher Partners Sydney, Justin has broad experience covering all areas of accounting, taxation and assurance. Particularly, Justin's areas of expertise are business services and outsourced accounting

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## Arthur Kollaras – Principal Engineer

*BSc Beng (Chem), PhilEng (Enviro), MIEAust, MISPE*

Highly qualified in chemical engineering and microbiology, has significant experience taking a new technology concept to pilot plant and full scale FDA standards and production internationally

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## Dr Justin Ward – Principal Quality Chemist

*BSc (Chem), PhD (Chem), MRACI, CChem*

A quality control expert who has worked with leading pharmaceutical companies, he is bringing Recce's research and development, and manufacturing up to US FDA requirements

# Economics of antibiotic development

A challenged business model – the antibiotic industry:

- ▶ Traditionally the more effective an antibiotic, the less likely it is to be used by clinicians who want to ‘save it’. Less use – less sales...
- ▶ Conventional antibiotics commonly suffer resistance quickly; investment in ‘new’ drug candidates a risk ROI
- ▶ Pharmco’s cutting antibiotic R&D – yet market need has never been greater

## How might one ‘unlock’ the anti-infectives industry?

- ▶ A new class of antibiotics – having a unique mechanism of action that DOES NOT lose effectiveness with ‘bacterial mutation’ – superbugs – even with repeated use
- ▶ Broad spectrum capabilities against deadly bacteria, Gr +/- and superbugs
- ▶ A drug that can be administered quickly, without impractical diagnostic delays, where clinical ‘guess-work’ could be a thing of the past!

Indications suggest RECCE® 327 may just be this needed change



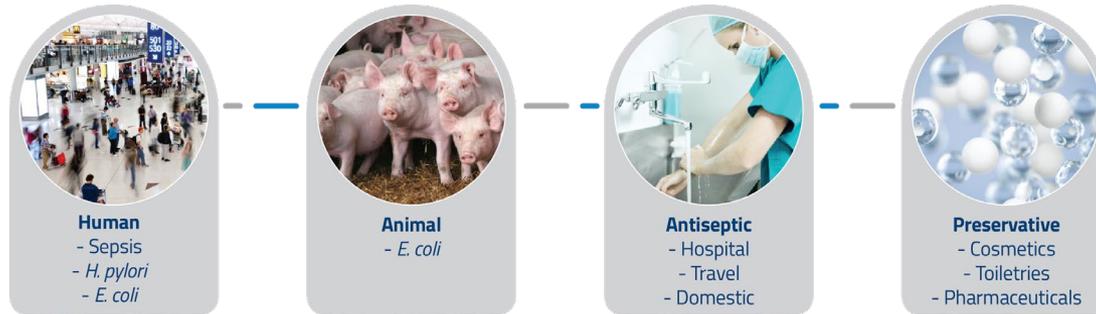
# US Legislative Support of Antibiotic Development

- ▶ US *Right-to-Try Act* passed in May/June 2018
- ▶ **Designed to give US patients with life threatening diseases, immediate and direct access to potentially lifesaving drugs** - that have completed Phase I clinical trials
- ▶ New legislation mitigates possibility of weeks of procedural delay - Previous legislation termed Compassionate Use
- ▶ **Potentially resulting in improved patient outcomes**
  - With reduced risk to those providing them
  - Potential to build earlier ‘direct’ distribution – diluting late-stage pharma market access model
- ▶ Further evidence of evolving regulatory environment in the US - Largest antibiotic market in the world
- ▶ Potential aimed at **expediting new drugs with lifesaving potential**
- ▶ Legislation does not affect Company’s business at present



# RECCE<sup>®</sup> Antibiotics – Technology

Recce's technology enjoys the added opportunity of multiple markets and product categories.



## Current RECCE<sup>®</sup> 327 development program



Estimated timelines/indications are subject to change in development plans and regulatory requirements/clarifications

FIH - First-in-human

\*Testing for RECCE<sup>®</sup> antibiotic Safety and Efficacy

\*\*Data submissions to regulators for permission to market

# RECCE<sup>®</sup> 327 overview

## Advantages unique to RECCE<sup>®</sup> antibiotics

- ▶ Avoids time-consuming diagnosis/guess work (patient survival decreases by 6% every hour left un-treated)
- ▶ Active against all tested superbug forms of bacteria
- ▶ Does not lose efficacy with repeated use
- ▶ New synthetic with **NO** superbugs against it
- ▶ New class of antibiotic
- ▶ First drug designed specifically for the treatment of sepsis

## Corporate advantages unique to Recce

- ▶ Extraordinary economy of production in only a few steps
- ▶ Production method very easily varied to produce different antibiotics for specific purposes
- ▶ Many variants to the Recce technology opens the opportunities and securities of alternative uses, e.g. *H. Pylori*, *E. coli*, virus, veterinary and antiseptic markets

# Investment summary



Qualified Infectious Disease  
Product (QIDP) Designation



Generating Antibiotics Incentive  
Now (GAIN) Act approved



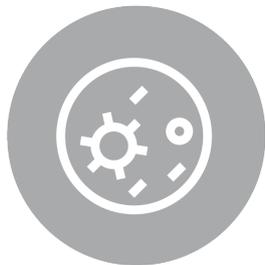
Proprietary technology as a  
new class of antibiotics



Lead compound addressing  
the most expensive condition  
faced by hospitals worldwide



Early commercialisation  
potential



Initial focus on sepsis-  
potentially the first treatment  
for sepsis



Favourable legislative and  
financial landscape



Experienced commercial  
management and board



Creating value by meeting  
key milestones



Established manufacturing  
(volumes suitable for Ph I/II)

# Thank you

**James Graham**  
Executive Director

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