ASX Announcement

Recce Pharmaceuticals
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Recce Delivers Opening R&D Address at 2019 World Antibiotic Resistance Congress

Sydney, Australia, 08 November 2019: Recce Pharmaceuticals Ltd (ASX: RCE) (**Recce** or the **Company**), developing a new class of synthetic antibiotics, today released its presentation at the World Anti-Microbial Resistance Congress in Washington D.C., 7-8 November 2019.

Picture: Chairman Dr Prendergast

Dr John Prendergast, Chairman of Recce Pharmaceuticals, today delivered the Opening R&D Address on ***"How synthetic antibiotic development can change the antibiotic treatment model"***. Supporting slides available below.

The Company has further been invited to Lead a Panel at the **Economist Anti-Microbial Resistance Summit Asia** Thursday 5 December 2019 in Singapore and looks forward to updating in due course.

Dr Prendergast's talk will be available in the coming weeks on the company's website.

Recce Pharmaceuticals

WORLD ANTI-MICROBIAL RESISTANCE CONGRESS 2019

ASX:RCE

How Synthetic Antibiotic Development Can Change The Antibiotic Treatment Model

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Antimicrobial Resistance Facts & Figures

19

Between 1980 and 1984, 19 new antimicrobial drugs were approved

12

Between 2000 and 2018, only 12 new antimicrobial drugs were approved, most of them additions to existing drug classes

80-90%

Resistance rates for specific bacterium-antibiotic combinations in certain countries

700,000

Each year, 700,000 people die globally due to antimicrobial resistance

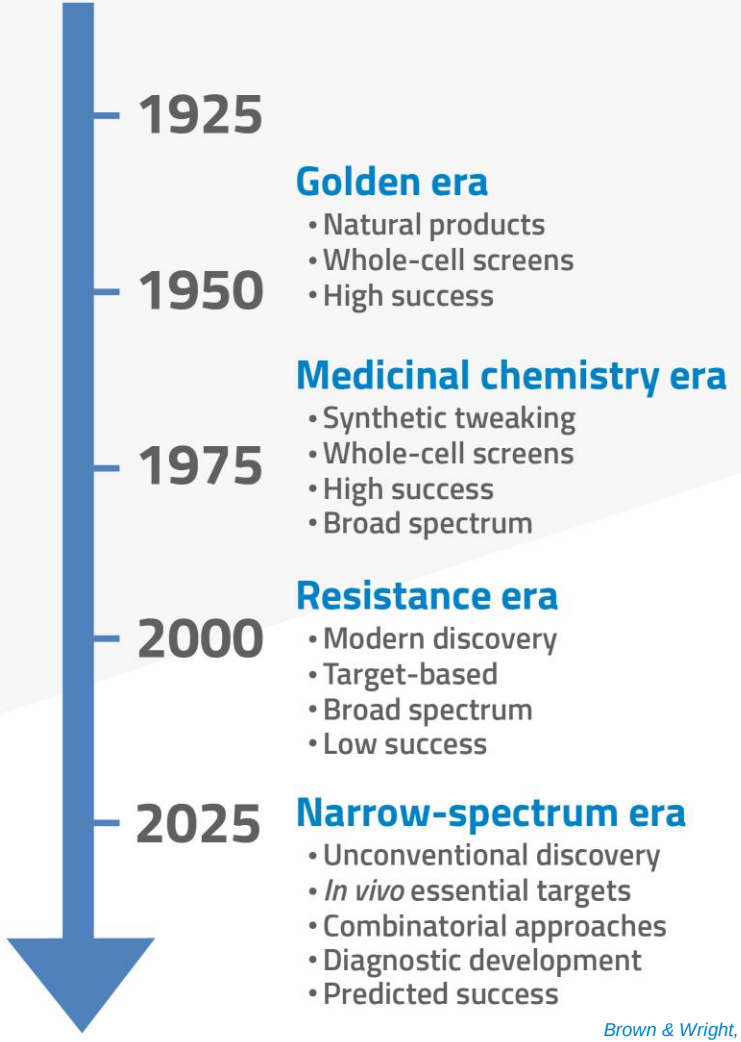
10 million

By 2050, it is believed that superbugs will kill up to 10 million people each year (this will supersede deaths projected from cancer)

2 million

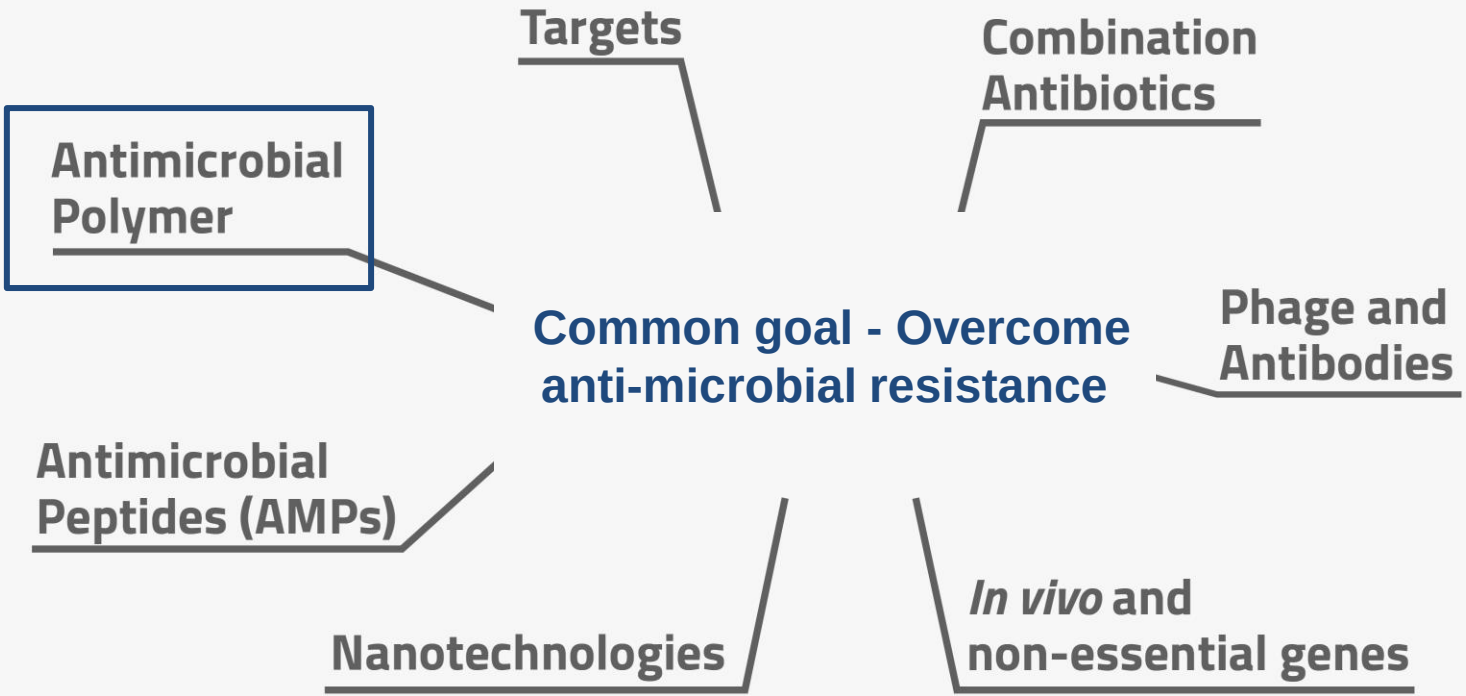
Every year, 2 million people in the US get an antibiotic-resistant infection, and at least 23,000 people die from it

Models of antibiotics drug discovery and development



Brown & Wright, Nature 2016

International Focus to Identify New Antibiotics



Primary Synthetic Anti-Bacterial Strategies

Antimicrobial Peptides (APs) – – – – – **Antimicrobial Polymers (AMPs)** – – – – – **Nanotechnologies**

- AMPs can either display antibacterial activities through its own inherent chemical structure; e.g., quaternary nitrogen groups, halamines and polylysine or can serve as a backbone to improve the potency of existing antibiotics.
- AMPs' design traditionally based on the chemical templates provided by Antimicrobial Peptides (APS), a class of peptides of the innate immune system which protects the body from invading pathogens.
- APs are relatively small in size (10–50 amino acids), amphiphilic with cationic charge. With these physical characteristics, APs accumulate on the cell membranes and form pores on the structure, thus killing the bacteria. With multimodal mechanisms of action, APs can resist acquired resistance by the bacteria.

Design Strategies for Novel Antibiotics

Type of Antibiotics	Delivery modalities	Manufacturing costs	Toxicity	Enzyme Degradation
Antimicrobial Peptide – based polymers (APs)	Yes	High	High	Yes
Antimicrobial Polymers (AMPs)	No	Low	?	No
Recce Pharmaceuticals	**Yes**	**Low**	**Acceptable**	**No**

THE distinguishing feature of RECCE antibiotics is its unique Mechanism of Action

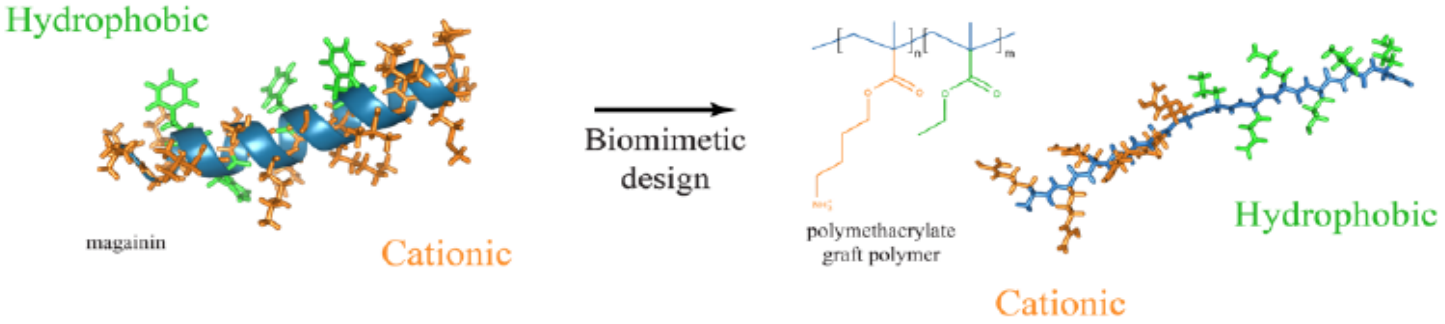
Design Strategies for Novel Antibiotics

Antimicrobial Peptides (APs)

Antimicrobial Polymers (AMPs)

Antimicrobial peptides

Antimicrobial polymers



- Many AMPS show significant efficacies against bacteria in vitro but had reduced potency when tested in vivo
- Despite their potential, AMP's application in the clinical setting have been hampered due to several pharmaceutical limitations such as: susceptibility to enzymatic degradation, poor bioavailability and toxicity

Natural antibiotics vs synthetic antibiotics

Natural antibiotics

Pre-formed
natural superbugs

- All Fungi or Bacteria based
  - "*Penicillin allergy is the most common drug allergy and is reported in up to 15 percent of hospitalized patients*"[1]
- Only as good as what's found in nature
- Has always had naturally occurring superbugs, now multiplying out of control!

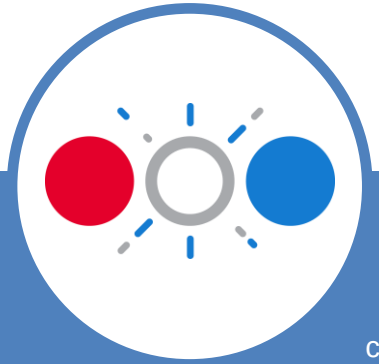
Synthetic antibiotics

NO Pre-formed
natural superbugs

- Entirely man-made and designed synthetically with purpose
- Universal Mechanism of Action - detailed experimentation demonstrates it does not succumb to superbugs.
- Broad Spectrum capability and maintains its activity even with repeated use!

[1] *https://www.uptodate.com/contents/choice-of-antibiotics-in-penicillin-allergic-hospitalized-patients/abstract/1*

RECCE® 327: *A New Class of Broad-Spectrum Antimicrobial Polymer to address antibiotic resistant Superbug Crisis*



Based on a unique composition – Copolymer of PEPP

Water soluble over a broad range of pH and essentially a net neutral charge

Kills Gram +ve & Gram –ve bacteria, including their superbug forms - even with repeated use.

Lead indication for treatment of sepsis – #1 most expensive condition.

Qualified Infectious Disease Product designation under GAIN Act.

10 years market exclusivity (post approval).

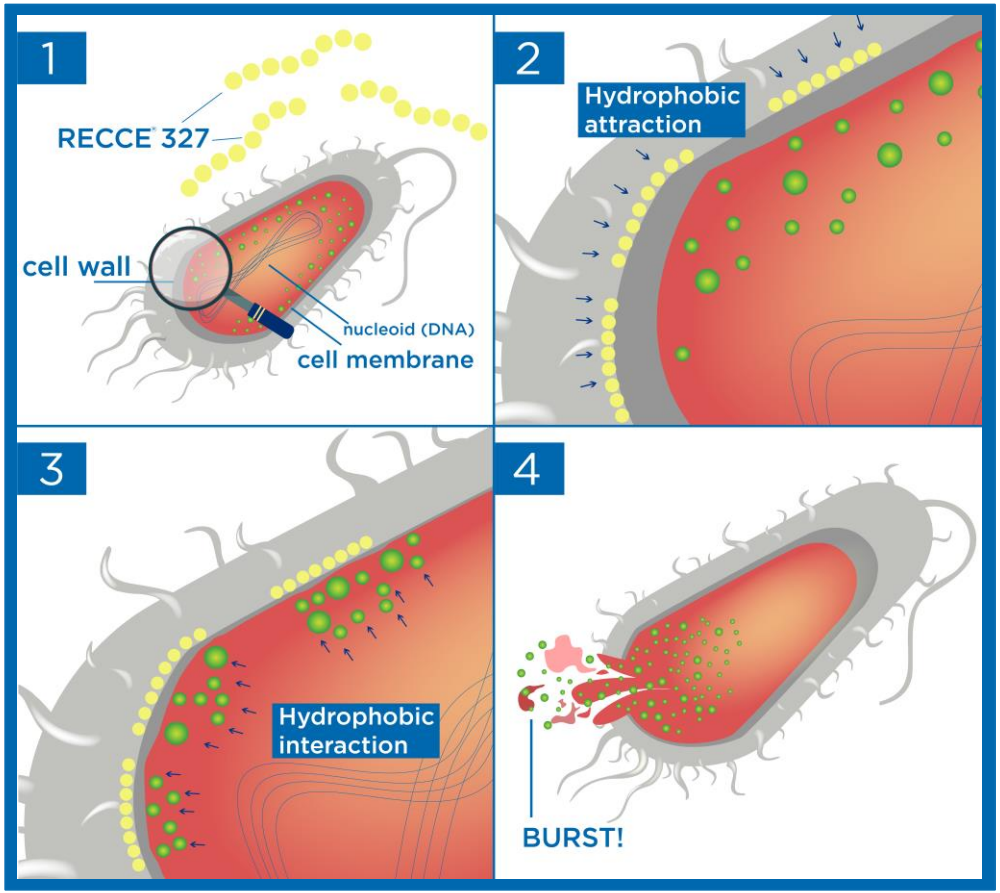
Fast track (life of regulatory process).

Patented manufacturing, producing to Phase I & II volumes.

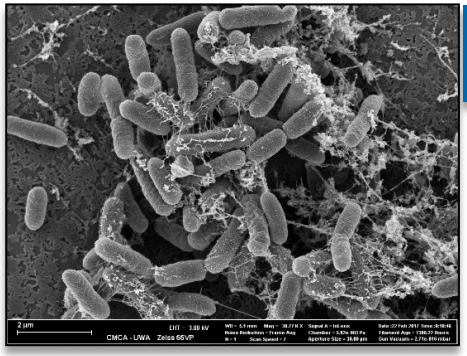
Tackling superbugs – RECCE® 327 (video)

RECCE® 327 – MoA

- RECCE® antibiotics are attracted to the bacteria plasma membrane through hydrophobic attraction
- An interaction occurs within the bacterial plasma membrane proteins via hydrophilic interactions
- Subsequent constriction of bacterial cell wall and the natural, unique high metabolic pressure in bacteria results in bacterial cell lysis
- Efficacy is **independent** of the mutation rate

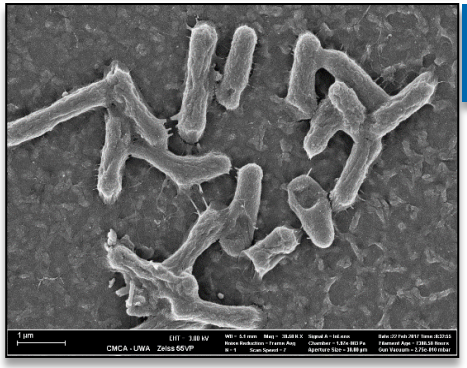


RECCE® 327 Mechanism of Action in practice



00:00 minutes

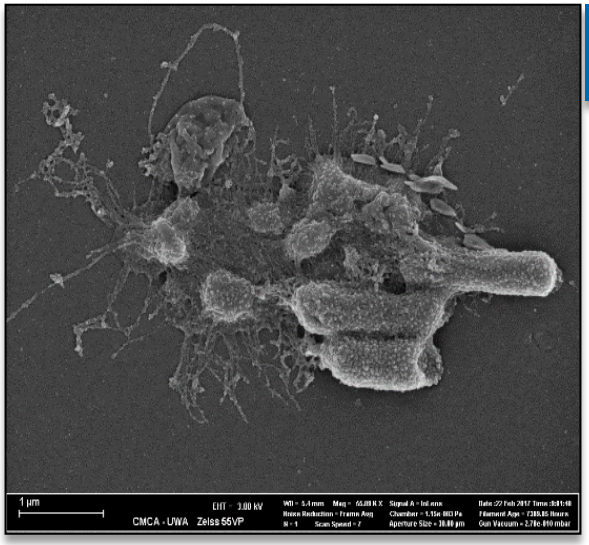
Before application of RECCE® 327, the *E.coli* bacteria cells are healthy, smooth and intact



20 minutes

After application of RECCE® 327, the *E.coli* bacteria cell membrane begins to weaken and disrupt

Some bacteria already distended and lysing



180 minutes

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

Bacteria bursting and now "mopped up" by host immune cells

This is a high-definition electron microscope image generated in February 2017 by Dr Peta Clode and Lyn Kirilak of the Centre for Microscopy, Characterisation and Analysis, University of Western Australia. It was taken to demonstrate RECCE® 327's unique mechanism of action

RECCE® antibiotics kill at practical speeds

Rates of kill of standard bacteria

S. aureus	*E. coli*	*P. aeruginosa*	*S. pyogenes*	*C. difficile*
20-60 minutes	20-60 minutes	3-24 hours	20-60 minutes	20-60 minutes

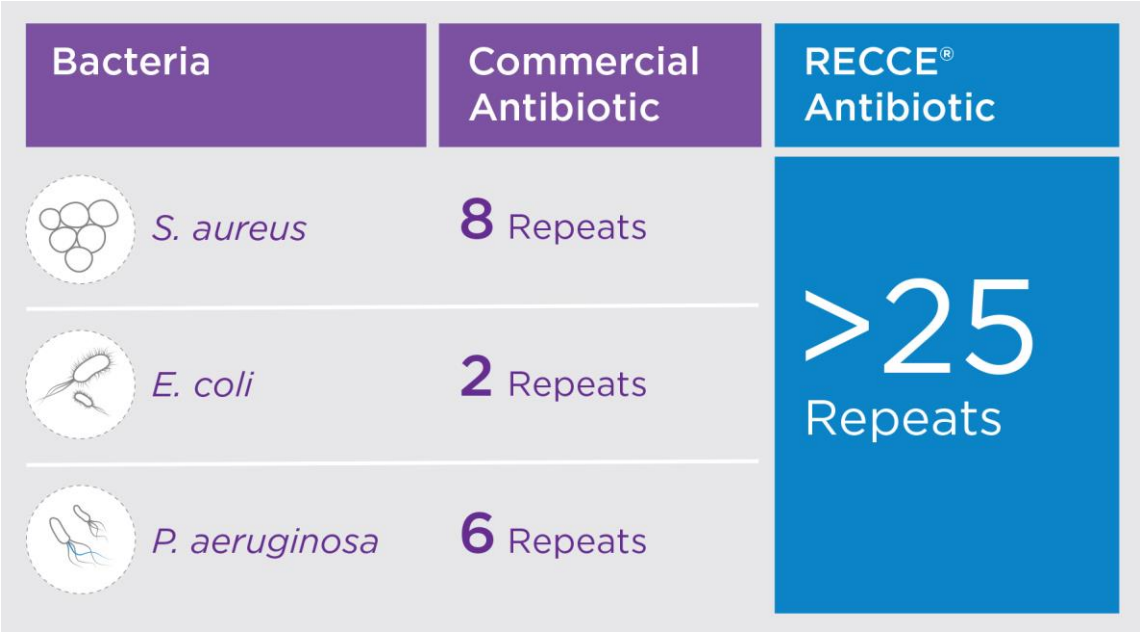
Rates of kill of Superbugs

S. aureus	*E. coli*	*P. aeruginosa*	
20-60 minutes	20-60 minutes	3-24 hours	**The same kill-rates for standard bacteria and their superbugs**

All concentrations of bacteria (germ) were 10^6 cfu/ml
Concentration of RECCE antibiotic was 1,000 ppm against all bacteria except P. aeruginosa
2,000 ppm was used against P. aeruginosa

RECCE® antibiotics repetitive use[1]

Number of repetitive uses before displaying loss of antibiotic activity



[1] After repetitive use, the commercial antibiotic loses activity; >25 repeats **RECCE® antibiotic DOES NOT**

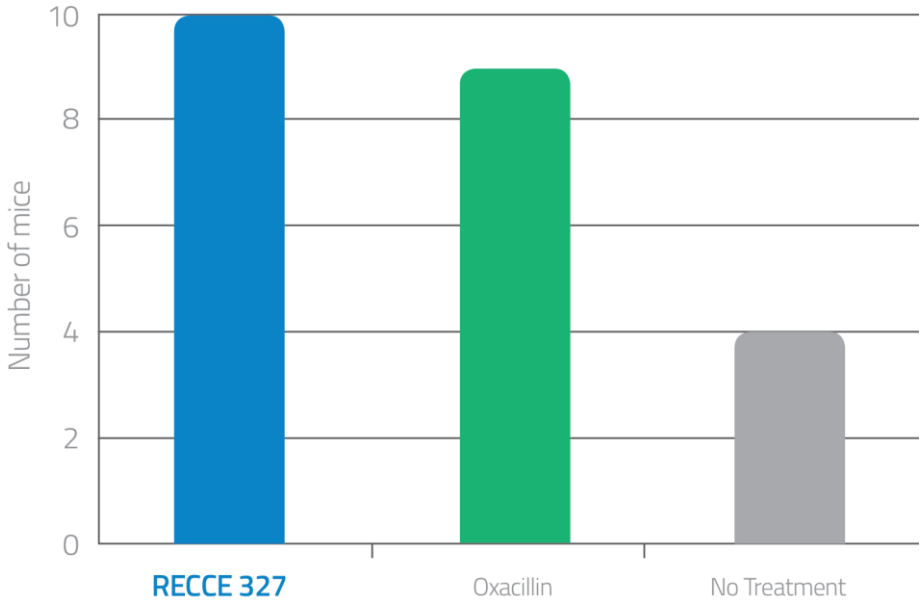
RECCE® Antibiotics – Curative study*

- Three groups of 10 mice were each infected with MRSA (*S. aureus* superbug)
- All ten mice treated with RECCE® 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® 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)*



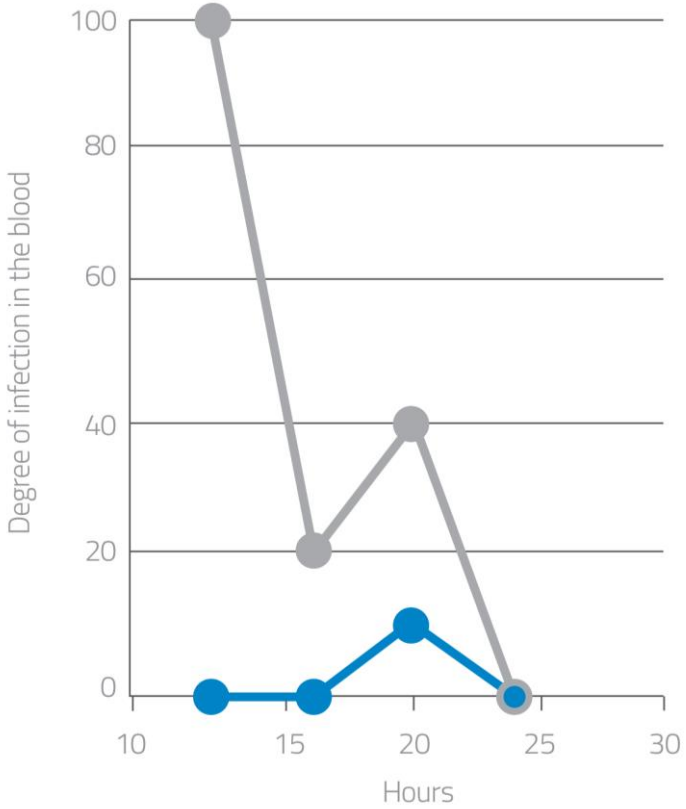
* Results from an independent laboratory in USA

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 12th hour (per industry standard) to allow bacterial infection to develop in host
- After the 12th 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

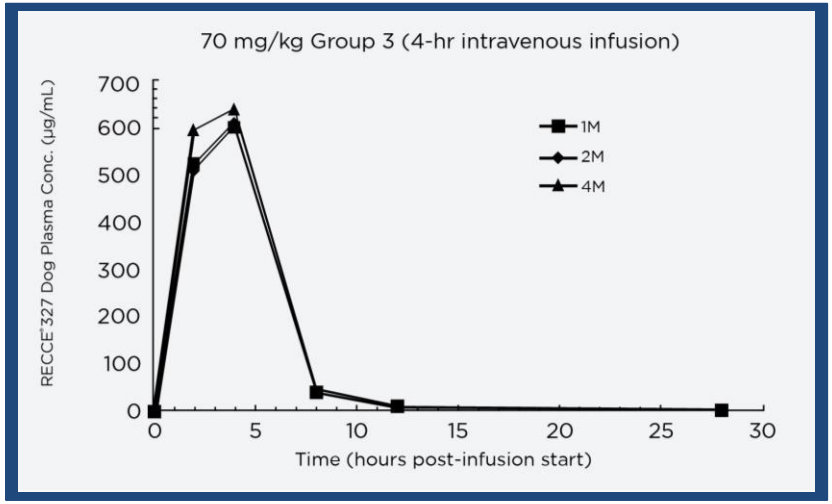
Sepsis in mice from *Streptococcus pyogenes*

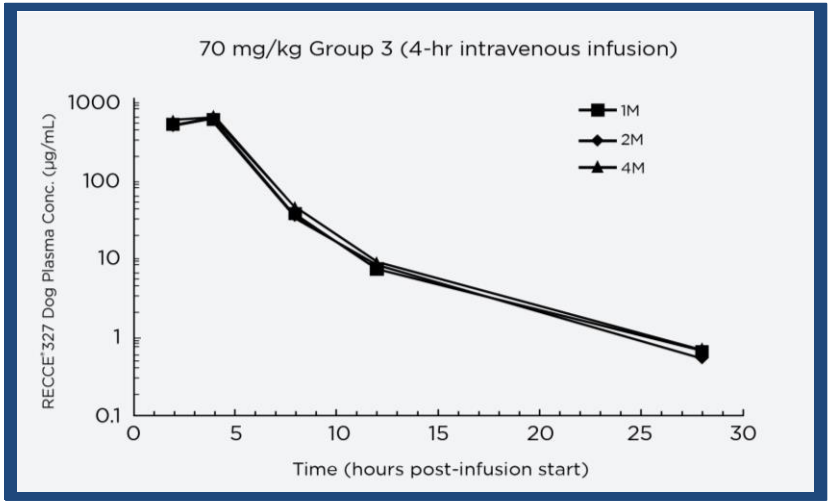


* Results from an independent laboratory in USA

Toxicity Study* – Beagle Dogs

A dose-range-finding and intravenous infusion toxicity study with RECCE® 327 in Beagle Dogs.





- Dogs administered RECCE® 327 (70mg/kg) over 4-hour IV infusion protocol
- Studies (*in-vitro* & *in-vivo*) indicate broad spectrum efficacy at 70mg/kg dose

- Compound again well identified in the blood
- High correlation between dose level and plasma concentration

*Results from an independent US laboratory

Patents and trademarks

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

Filed	Patent Family 1 Granted	Expiry	Patent Family 2/3	Expiry	Trademarks registered
Australia	✓	2028	✓	2035	✓
USA	✓	2029	✓	2035	✓
Europe	✓	2028	✓	2035	✓
Germany	✓	2028	✓	2035	-
Spain	✓	2028	✓	2035	-
France	✓	2029	✓	2035	-
United Kingdom	✓	2028	✓	2035	-
Italy	✓	2028	✓	2035	-
Sweden	✓	2028	✓	2035	-
Japan	✓	2028	✓	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 $/KG
- **No expensive waste** – 99.9% product yield.

- Automated **manufacture process taking approximately 1 ¼ hours**.
- **500 doses** per automated manufacture output in less than 1 hour/run

- Currently producing in **volumes to support** planned **Phase I & II clinical trials**.

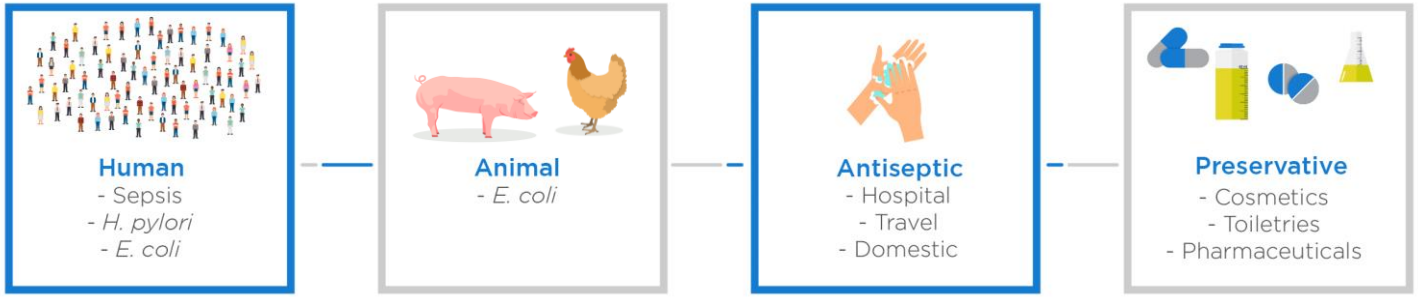
- Facility built to pharmaceutical specification.
- Packaging and labelling to international 'tamper-proof'

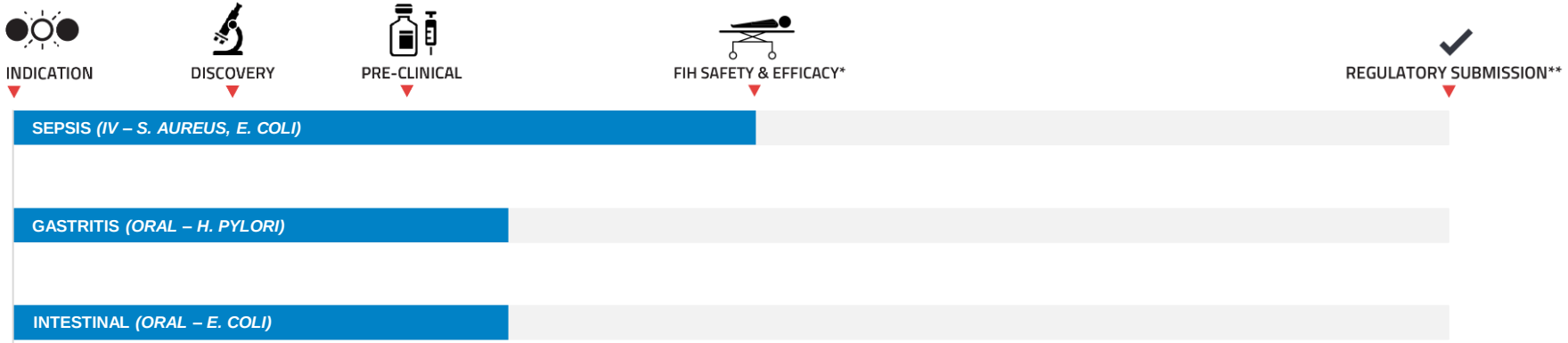
Snapshot for RECCE® 327

- ✓ Efficacy – Performs as a broad spectrum antibiotic – active against Gram-negative, Gram-Positive and drug resistant Superbugs
- ✓ Safety – Toxicology & Dose Escalation studies in four animal species (2 small, 2 large) - Escalating dose, Maximum dose, Repeat Dosing
- ✓ Haemolysis – Selective toxicity against bacteria in the bloodstream
- ✓ Genotox & Mutagenicity cleared – multiple studies confirm does not cause cell mutation
- ✓ Pharmacokinetics – RECCE® 327 clears rapidly from blood stream after dosing
- ✓ Allergenicity – Unlike most existing antibiotics, anaphylactic reactions not evident
- ✓ Mechanism of Action – Unique (MoA) always works, unable to be overcome by bacterial mutation (superbugs) – even with repeated use!
- ✓ 100% Soluble at all pH's – 100% soluble at all pH's – even to the very acidic (low) pH of the stomach
- ✓ Chemistry, Manufacturing & Controls (CMC) – Established (wholly owned) to human clinical specification (GLP/GMP)
- ✓ First-in-human applications in preparation

RECCE® 327 development program

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





Estimated timelines/indications are subject to change in development plans and regulatory requirements/clarifications
FIH – First-inhuman
*Testing for RECCE ® antibiotic Safety and Efficacy
**Date submissions to regulators for permission to market

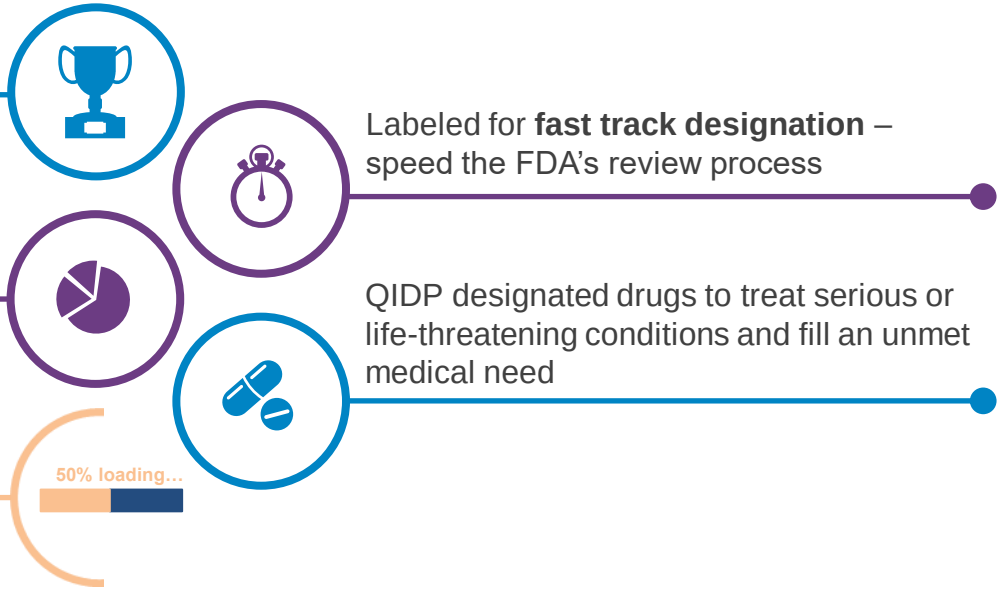
RECCE® 327 recognized as a Qualified Infectious Disease Product

- *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*."

Legal status awarded under ***US Generating Antibiotic Incentives Now (GAIN) Act***

10 years market exclusivity, starting from the date of New Drug Application approval

Anticipated further five-year exclusivity under **New Chemical Entity (NCE)** policy*



Labeled for **fast track designation** – speed the FDA's review process

QIDP designated drugs to treat serious or life-threatening conditions and fill an unmet medical need

*A New Chemical Entity (NCE) can be defined as "a compound which, previously, hasn't been described in scientific literature"

Australia's TGA Special Access Scheme

- The Special Access Scheme (SAS) refers to arrangements that provide for the import and/or supply of an unapproved therapeutic good for a single patient, on a case by case basis.

3

categories

Category A

- Pathway that may be accessed by a prescribing medical practitioner or by a health practitioner acting on behalf of that medical practitioner, for a patient, who is seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment.

Category B

- Application pathway that can be accessed by health practitioners if patients do not fit the Category A definition.

Category C

- Notification of use of specific therapeutic goods; allows certain types of health practitioners to supply therapeutic goods deemed to have an established history of use.

Australian Government

Department of Health

Therapeutic Goods Administration

Facts & Figures

27 million

Global burden – approx. 27 million people per annum develop sepsis

Recce's Mission: An urgent need for a new sepsis treatment.

Top 10

Leading cause of death in intensive care units and a top 10 cause of mortality worldwide

$20 billion

Sepsis represents a significant pharmaco-economic burden of >US$20 billion in annual hospital costs

750,000

In the US, 750,000+ cases of severe sepsis are recorded every year

Increasing

Care is improving but the incidence of severe sepsis is increasing rapidly

215,000

In the US, 215,000 deaths from sepsis are recorded every year

2%

Two per cent of hospitalisations are for sepsis but they make up 17 per cent of hospital deaths

Opportunity

High incidence means the potential market for effective treatments is sizeable

Expensive

Sepsis is the single most expensive condition treated in US hospitals

Thank you

John Prendergast, Ph. D.
Chairman

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