Recce Pharmaceuticals

# *James Graham - Executive Director*

***Finance News Network***
***Investor Event, Sydney***

FINANCE NEWS NETWORK

**September 2019**

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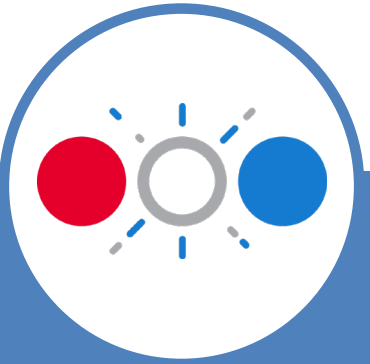
# About Recce Pharmaceuticals Ltd

*Recce Pharmaceuticals is commercialising a New Class of Broad Spectrum antibiotics to address the global health issue of antibiotic resistant superbugs.*



Listed on ASX 2016
**(ASX:RCE)**

New Class of Broad Spectrum antibiotics that kill Gram + and Gram – 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).

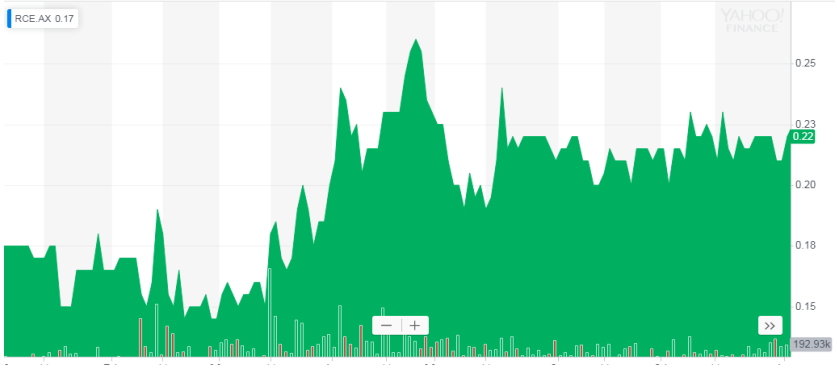
Patented manufacturing, producing to Phase I & II volumes.

# Recce Pharmaceuticals Ltd - Capital structure

## Major shareholders 31 July 2019

| | | |
|---|---|---|
| 1. | G. & O. Melrose* | 28.3% |
| 2. | R. Gustafson | 4.2% |
| 3. | Acuity Capital Investment | 4.2% |
| 4. | J. Graham* | 4.0% |
| 5. | Foord Asset Management | 3.9% |

## ASX:RCE 3 months




** Held by Executive Directors*

## Snapshot

| | |
|---|---|
| ASX code | **RCE** |
| Shares on issue | **107.13 million** |
| Share price | **AUD 21.5 cents** |
| Market Cap (approx.) | **AUD $23 million** |
| Cash and deposits* August 2019 | **AUD $403K** |
| Trading range 52 week | **AUD 13-26.5 cents** |
| Average daily volume 3 months | **117.94K** |

ShawandPartners

**R&D rebate to further offset this amount*

# Tackling superbugs – RECCE® 327 (video)

# Sepsis – it's a big problem!

**Sepsis** affects **30 million+ people** worldwide*

**270K deaths** recorded in the US yearly

**$24bn** in **annual costs** treated in US hospitals

- Sepsis is a life threatening inflammatory response to infection that has spread in the body[1].
  - Kills more people in the US than **prostate**, **breast** and **lung cancer** combined[2].
- **Most expensive condition to treat** - double the average cost per stay across all other conditions[3]
- Over 750,000 cases of severe sepsis reported in the US alone[4].
- ***Currently no drug therapies specifically for the treatment of sepsis.***[5]



*1 – Mayo Clinic*
*2 – Sepsis Alliance*
*3,4,5 – National Centre for Biotechnology Information*

**growing at an annual rate of 8-13%*

# 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 with purpose
- Universal Mechanism of Action - detailed experimentation demonstrates it does not succumb to superbugs.
- Contains only what we want - not reliant on what's found in nature
- 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*

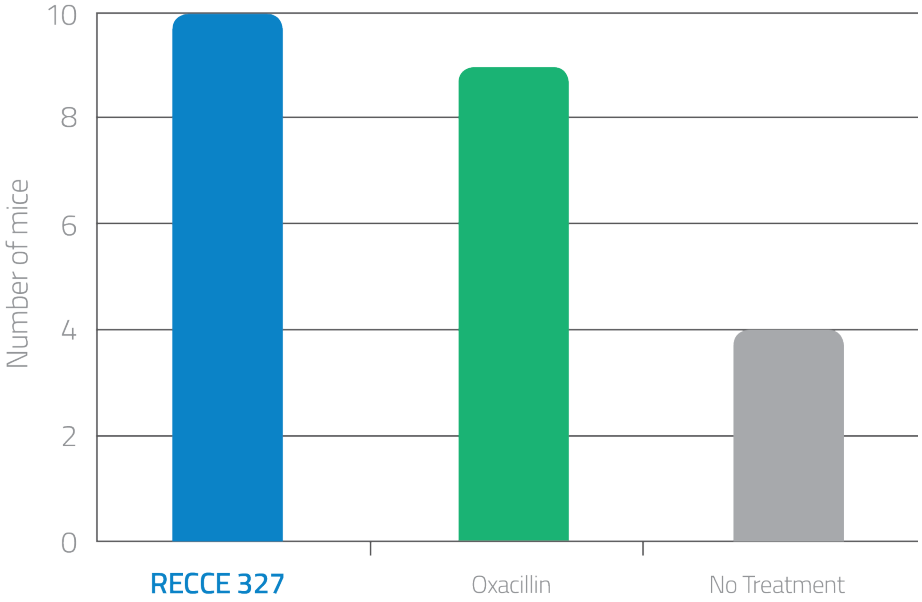
# RECCE® Antibiotics – Curative study*

- 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)***





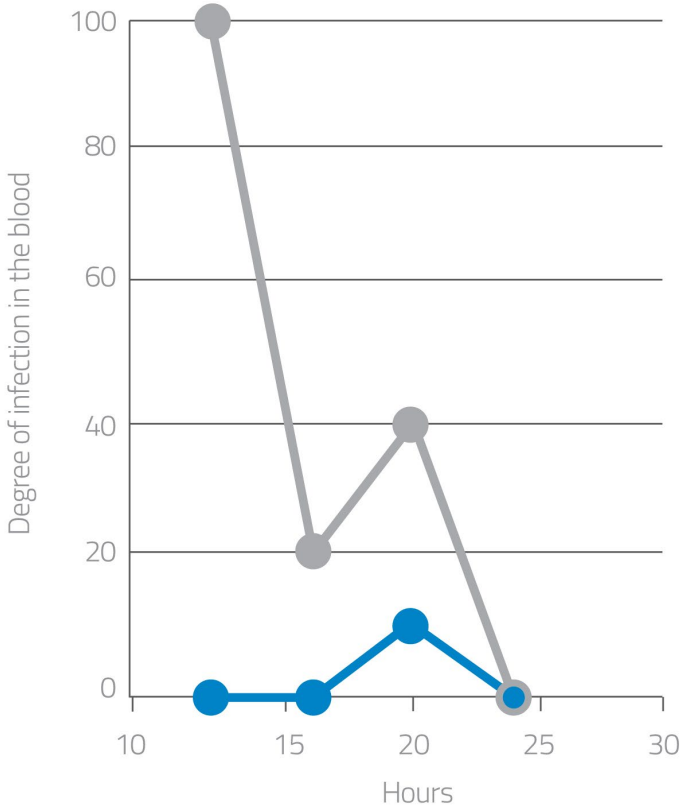

* Results from an independent laboratory in USA

# 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***

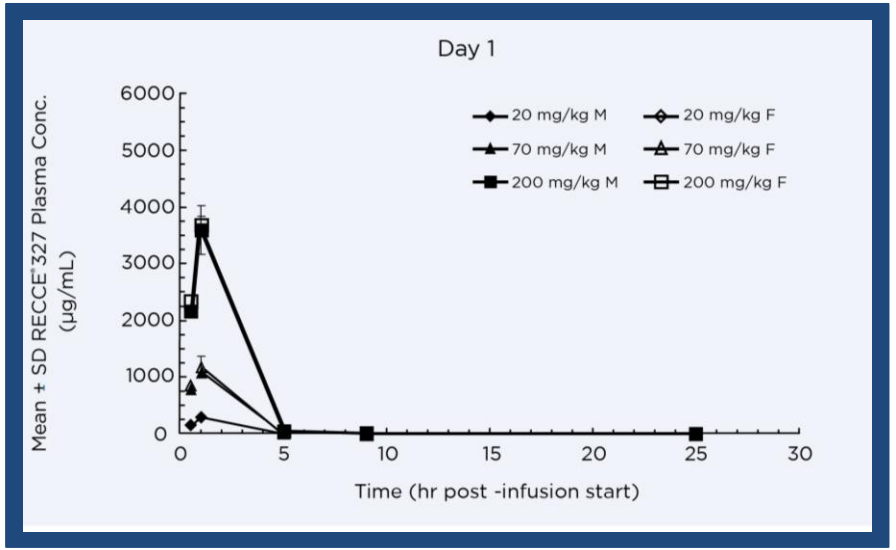




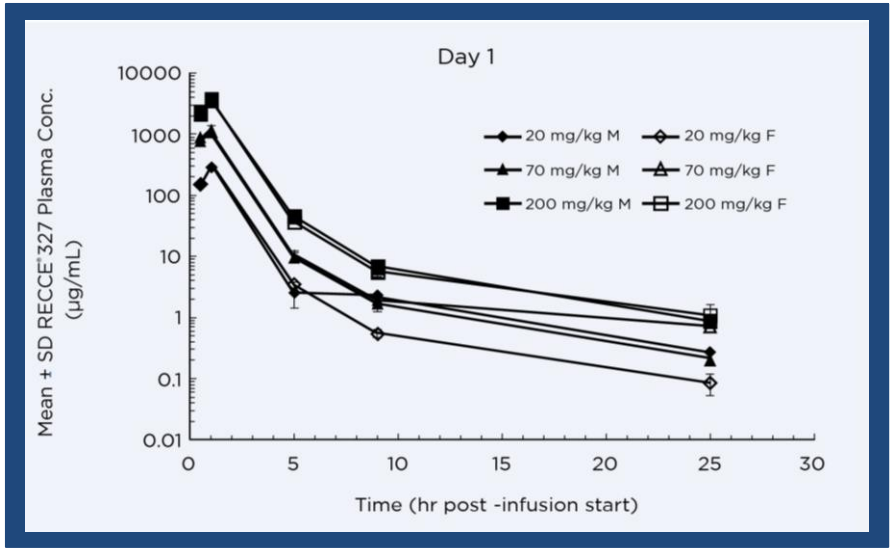

* Results from an independent laboratory in USA

# Toxicity Study* – Sprague Dawley Rats

*A dose-range-finding and 7-day repeat dose intravenous infusion toxicity study with RECCE® 327 in Sprague Dawley Rats.*




1-hour infusion - Rat plasma concentration of RECCE® 327 is dose dependent.




Following the 1-hour infusion – quickly cleared from the blood

✓ '**Dose Dependent**' = drug **concentration in blood can be well controlled** to **efficaciously kill pathogenic bacteria**;

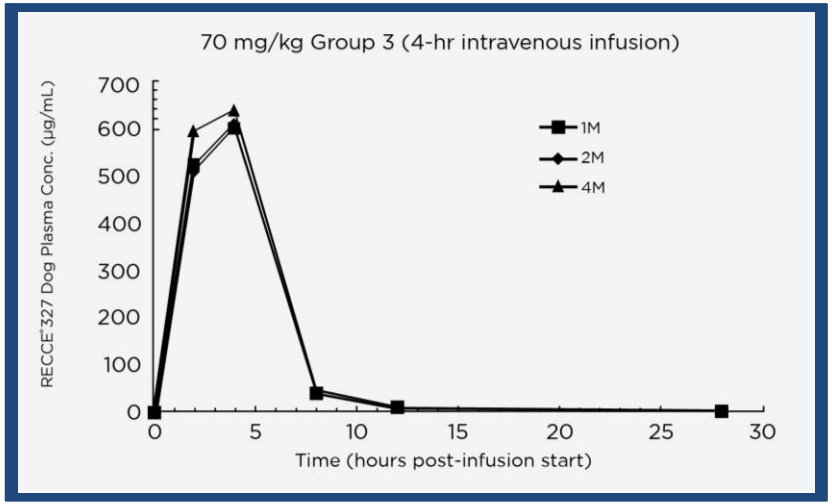
✓ '**Cleared from blood quickly**' = drug does it job in the bloodstream, then **exits quickly so as not to remain and cause toxicity**.

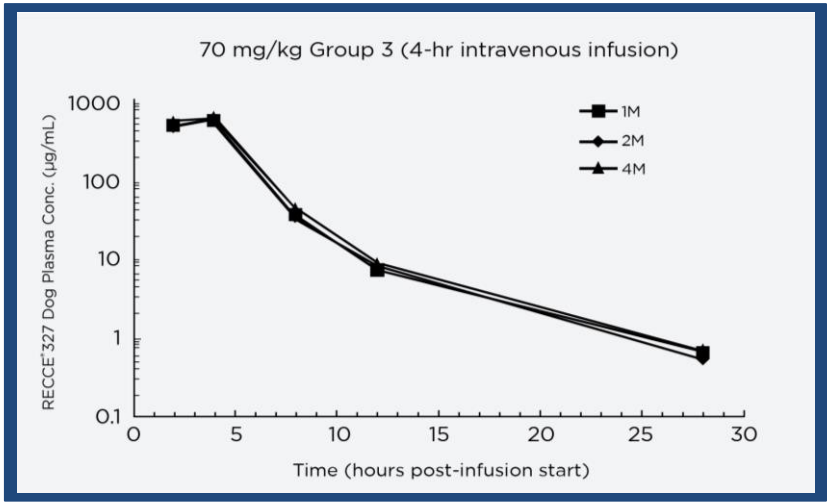


*Results from an independent laboratory in USA

# 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
- Numerous studies (*in-vitro* & *in-vivo)* indicate broad spectrum efficacy at 70mg/kg dose

- Even at highly zoomed level of analysis:
  1. Compound again well identified in the blood;
  2. High correlation between dose level and plasma concentration





*Results from an independent laboratory in USA

# 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 do not Fail[1]

Recce Pharmaceuticals

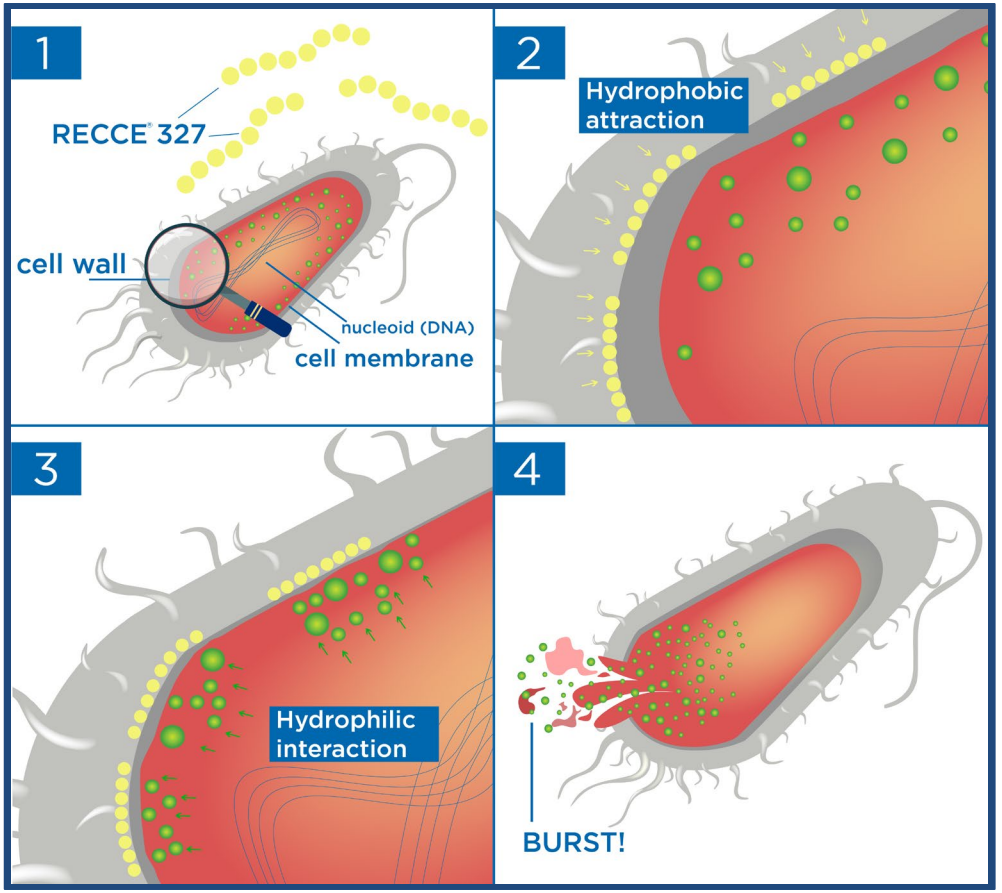
**Number of repetitive uses before displaying loss of antibiotic activity**

| Bacteria | Commercial Antibiotic | RECCE® Antibiotic |
|---|---|---|
| *S. aureus* | 8 Repeats | >25 Repeats |
| *E. coli* | 2 Repeats | |
| *P. aeruginosa* | 6 Repeats | |

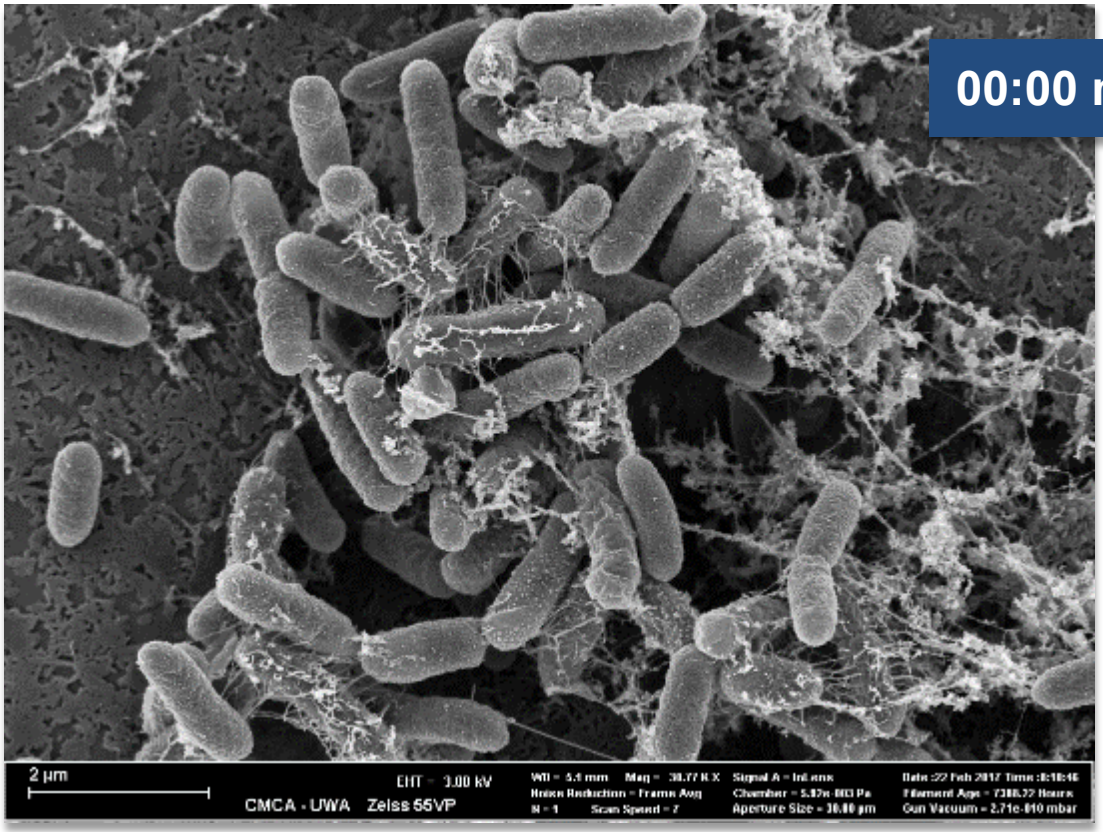
[1]After repetitive use, the commercial antibiotic loses activity; >25 repeats **RECCE® antibiotic DOES NOT**

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

- RECCE® antibiotics attracted to the bacteria plasma membrane through hydrophobic attraction
- An interaction occurs within the bacterial plasma membrane proteins via hydrophilic interactions
- Subsequent narrowing of bacterial cell wall and the natural, unique high metabolic pressure in bacteria results in bacteria cell lysis (BURST!)
- Outer protein can mutate as much as it likes (superbug) - RECCE® antibiotic will still kill it!



# RECCE® 327 Mechanism of Action in practice

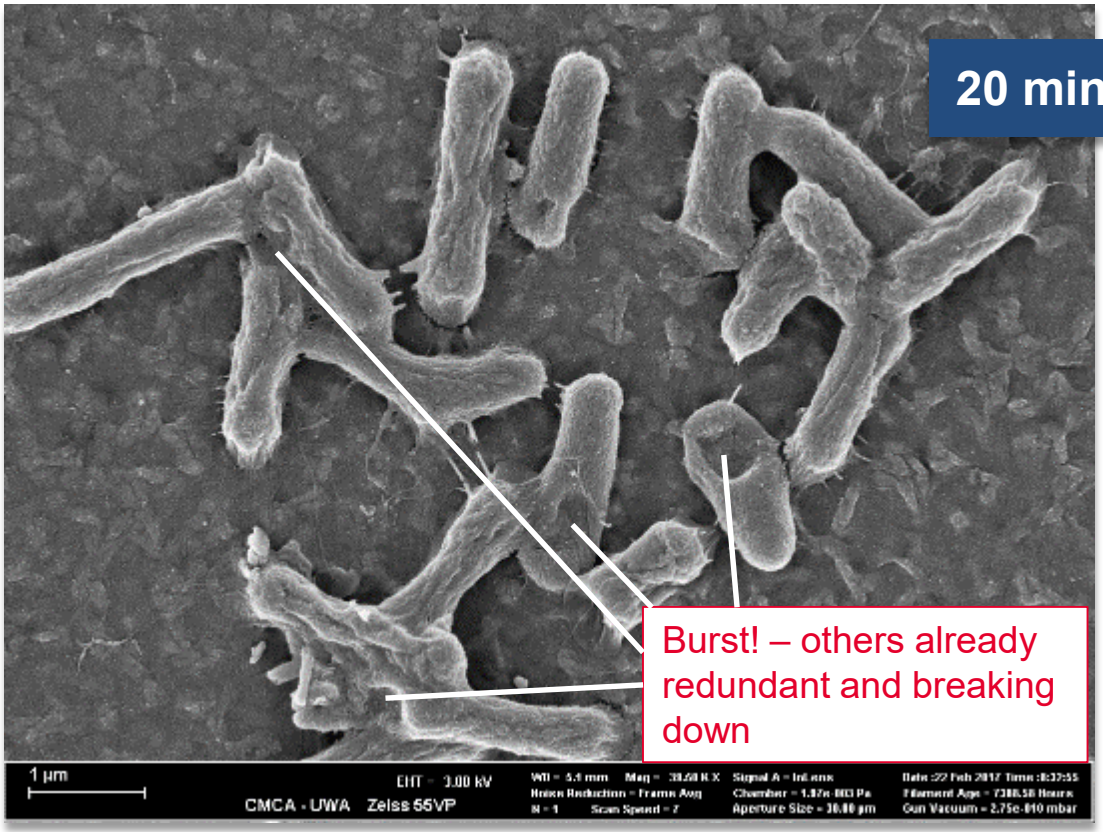



Before application of RECCE® 327, the *E.coli* bacteria cells are healthy, smooth and intact

recce.com.au

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

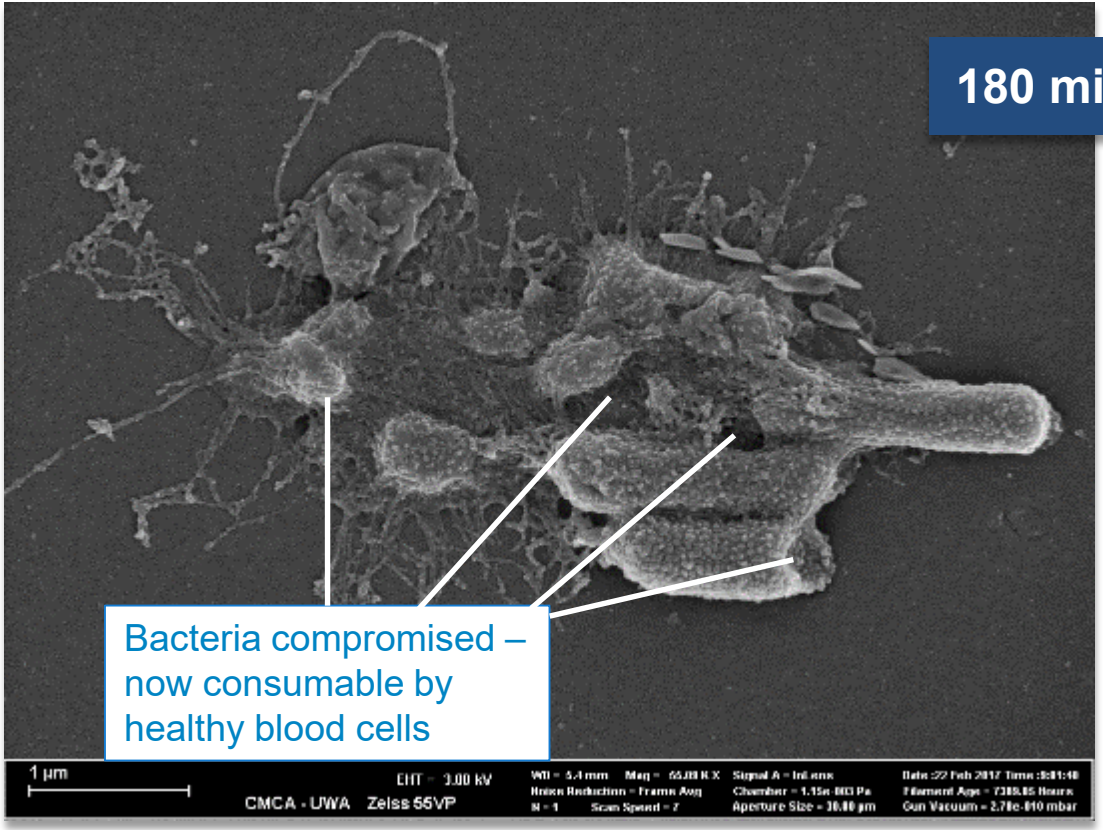
# RECCE® 327 Mechanism of Action in practice




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

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® 327 Mechanism of Action in practice




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

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

# New Antibiotic Checklist – 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 advanced stages

# What is 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"

# 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 | 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 $/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'

# Board and management structure

**Dr John Prendergast** – Non-Executive Chairman
*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

**Dr Graham Melrose** – Executive Director & 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

**Michele Dilizia** – Executive Director
*BSc (Med Sci), Grad Dip Bus (Mkting), BA (Journ), GAICD, MASM*
Co-inventor and qualified medical scientist; specialisation in medical microbiology and regulatory affairs

**James Graham** – Executive Director
*BCom (Entrepreneurship), GAICD*
Extensive experience in marketing, business development and commercialisation of early stage technologies with global potential

**Dr Justin Ward** – Executive Director & 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

**Alistair McKeough –** Company Secretary (Outsourced – **Automic Group)**
Alistair is a qualified lawyer and Principal of Automic Legal Pty Ltd, Alistair has broad experience as a commercial litigator and Company Secretary to ASX Listed companies

**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

**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

**Dr David Bowers –** Chair of Clinical Advisory Committee
Leading spinal injury physician at Royal North Shore Hospital. Dr Bowers has a specialist interest in the treatment of complex and life-threatening antibiotic resistant infections, particularly among patients with severe spinal cord injuries.

# 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

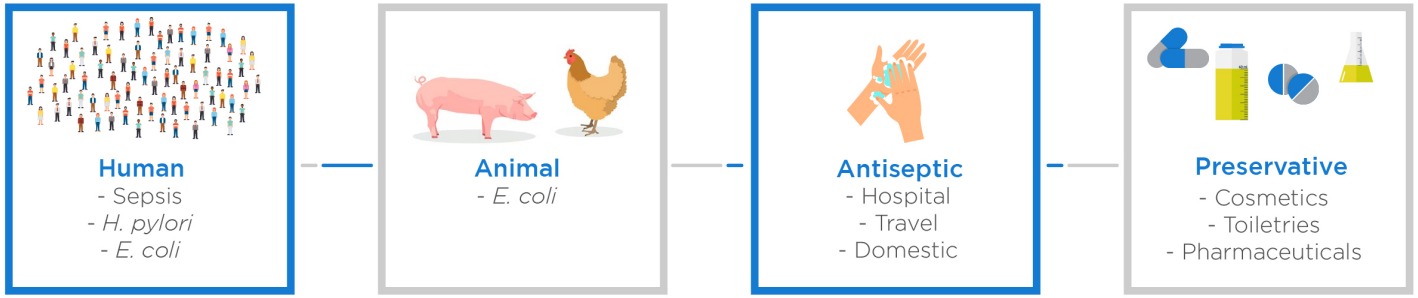
# World Anti-Microbial Resistance Congress 2019

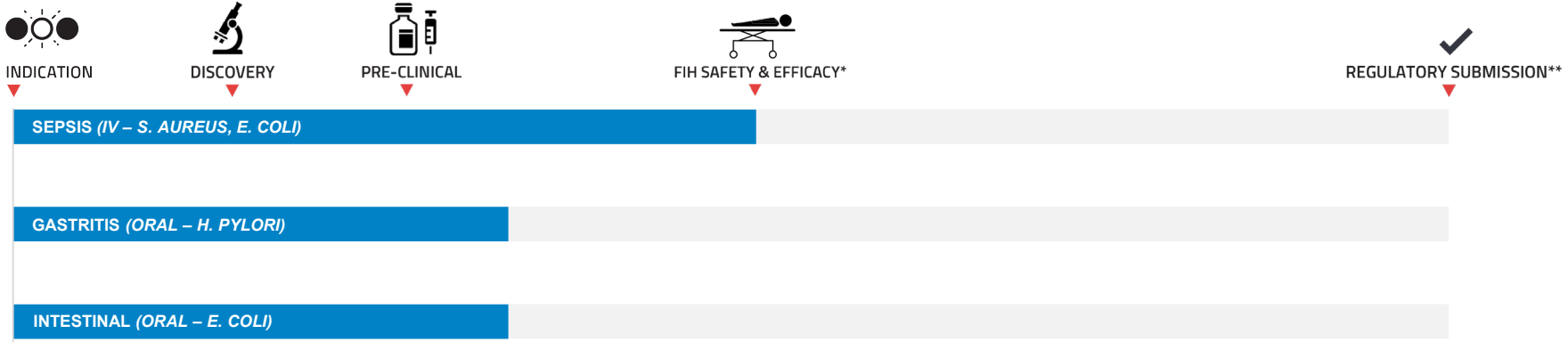
- **Sole commercially focussed AMR conference globally**
- Recce **Opening R&D Address** - Chairman Dr John Prendergast
  - ***"How synthetic antibiotic development can change the antibiotic treatment model"***
- More than 600 attendees from over 40 countries
- Congress General Manager on Recce:
  - *"We are proud to provide this platform for promising antibiotic programs to be introduced to the AMR community, such as Recce Pharmaceuticals' synthetic polymer program which has the potential of transforming the way superbugs are targeted, through a new class of broad-spectrum antibiotics."*


***World Anti-Microbial Resistance Congress 2018***
***Left to right: Dr Prendergast, Ms Dilizia, Mr Graham***

# 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

# 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

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