



***Corporate  
Presentation***  
**ASX:RCE**

**August 2020**

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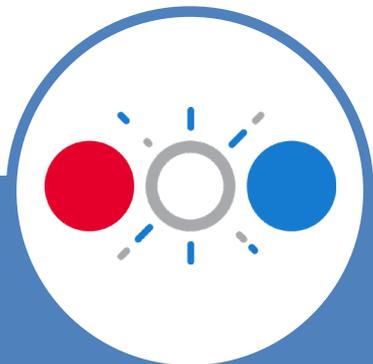
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# About Recce Pharmaceuticals Ltd

*Recce Pharmaceuticals (ASX:RCE) is commercialising a New Class of Synthetic Anti-Infectives to address the global health issue of antibiotic resistant superbugs and emerging viral pathogens.*



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



New Class of Synthetic Anti-Infectives that kill emerging viral pathogens as well as Gram + and Gram – bacteria, including their superbug forms - even with repeated use!

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



RECCE® 327 awarded 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 30 July 2020

1. G. & O. Melrose*	25.3%
2. Vesty Superannuation	4.9%
3. J. Graham**	3.6%
4. Acuity Capital Investment	3.1%
5. JP Morgan Nominees	3.0%
6. M. Dilizia**	2.2%



## Snapshot

ASX code	RCE
Shares on issue 30 July 2020	144.17 million
Share price 30 July 2020	AUD \$1.35
Market Cap (approx.) 30 July 2020	AUD \$194.6 million
Cash and deposits 30 July 2020 Ex - Anticipated R&D Funds	AUD \$2.63 million
Trading range 52 week	AUD 0.20c - \$1.52
Average daily volume 3 months	582.11K
Debt	Nil

\* *Inventor & Former Head of J&J Research (Australasia)*

\*\* *Held by Executive Directors*



# 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

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## Dr Alan Dunton – Non-Executive Director

*BSc (BioChem) Hons, M.D. (NYU)*

US based, Director of Palatin Technologies. Over three decades of senior pharmaceutical experience incl. President and MD of Janssen Research Foundation (J&J Research). Dr Dunton has advanced a number of blockbuster antibiotics through regulatory review and commercialization at fortune 500 companies including J&J and Roche.

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## 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

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## James Graham – Executive Director

*BCom (Entrepreneurship), GAICD*

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

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## 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

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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 & Head of Manufacturing

*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 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.

# RECCE® – Multiple Anti-Infective Applications

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



INDICATION



DISCOVERY



PRE-CLINICAL



FIH SAFETY & EFFICACY



REGULATORY SUBMISSION

## Intravenous Administration

Phase I/IV study expected patient dosing 2HCY 2020

- ▶ Severe Sepsis – Blood poisoning
- ▶ Pre Sepsis – Kidney and UTI infections

## Topical Administration

Topical study app. presented to WA Trial Ethics Committee

- ▶ Skin and Skin Structure Infection – Wound Infection, Contraction

## Viral Indications

RECCE® 327 dispatched to CSIRO, RECCE® 327 & RECCE® 529 dispatched to Path BioAnalytics

- ▶ Influenza A and other significant respiratory infections
- ▶ R327 Priority 1 Candidate Group – SARS-CoV-2 Antiviral Program with CSIRO and The Peter Doherty Institute
- ▶ Path BioAnalytics & leading US academic institution to evaluate R327 & R529 anti-viral activity in SARS-CoV-2



## Other Indications

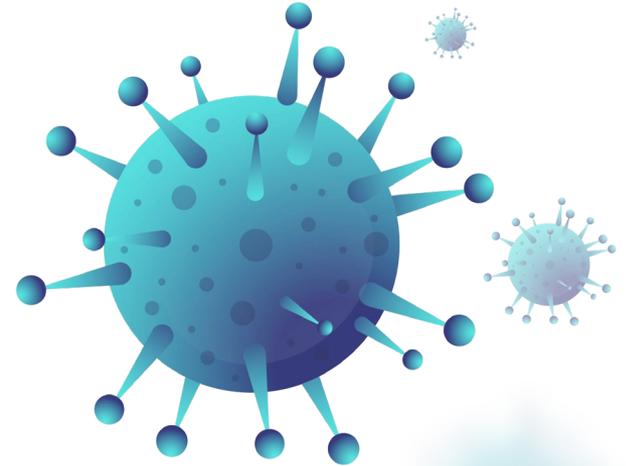
New RECCE® 435 compound being evaluated in animal model studies

- ▶ Gastritis (*H. pylori*)
- ▶ Reproductive Organs (*N. gonorrhoeae*)



# RECCE<sup>®</sup> 529 – New Antiviral Compound

- ▶ **RECCE<sup>®</sup> 529** is a new synthetic polymer formulation with indication against viruses
- ▶ Compound built on Recce's anti-infective expertise
- ▶ **RECCE<sup>®</sup> 529** 100% water soluble at all pH levels in its liquid form
- ▶ **RECCE<sup>®</sup> 529** to be tested in SARS-CoV-2 study in an ex-vivo respiratory organoid model system
- ▶ **No proven vaccine or therapeutics currently available for COVID-19**
- ▶ Recce will continue to expand upon this promising indication in due course
- ▶ Product pipeline continues to strengthen and expand in order to find a treatment for 'difficult to treat' viral infections



# 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”<sup>1</sup>*
- ▶ 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!

# Sepsis – it's a big problem!

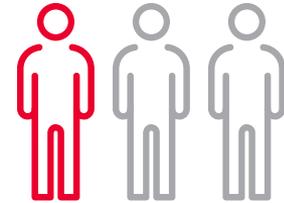
48.9 million incident cases of **sepsis** recorded worldwide<sup>1</sup>



11 million sepsis related **deaths** recorded<sup>2</sup>



**One in three** patients who **die** in hospital have sepsis<sup>3</sup>



- ▶ Sepsis is a life-threatening inflammatory response to infection that has spread in the body.
  - Kills more people in the US than **prostate, breast** and **HIV/AIDS** combined.<sup>4</sup>
- ▶ Has been the **most expensive condition to treat** in the last 8 years - **double the average cost per stay across all other conditions.**<sup>5</sup>
- ▶ **Currently no drug therapies specifically for the treatment of sepsis.**<sup>6</sup>

1,2,3 – The Lancet

4 – BioMed Central

5 – University of Texas

6 – International Medicine Journal RACP

# RECCE<sup>®</sup> 327 Phase I Human Clinical Trial

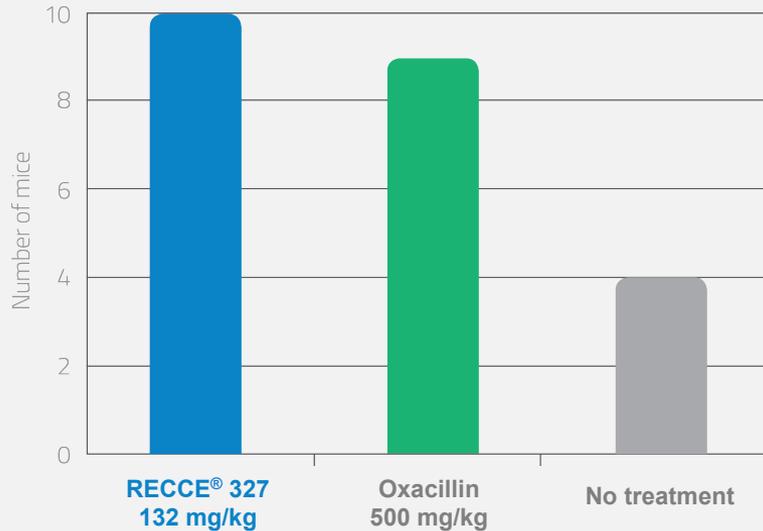
- ▶ Human safety and tolerability study to assess I.V infusion of RECCE<sup>®</sup> 327 in 40 healthy subjects as a single ascending dose
- ▶ Phase I trial agreement with leading clinical research organization PAREXEL
- ▶ First patients expected to be dosed in second half of 2020
- ▶ Estimated clinical start-to-completion with data read-outs less than 12 months from now



- ▶ First-in-human **self-dosing** by a respected NSW physician
- ▶ Self-dosing treatment showed **No Observed Adverse Effect Levels**
- ▶ Escalation of 1ml undiluted (neat) RECCE<sup>®</sup> 327 via buccal administration.
- ▶ Blood samples taken & analysed for haematology and clinical biochemistry parameters
  - ▶ **Results found to be normal**
- ▶ Further analysis expected to be taken on samples to determine concentration levels of RECCE<sup>®</sup> 327 in the blood

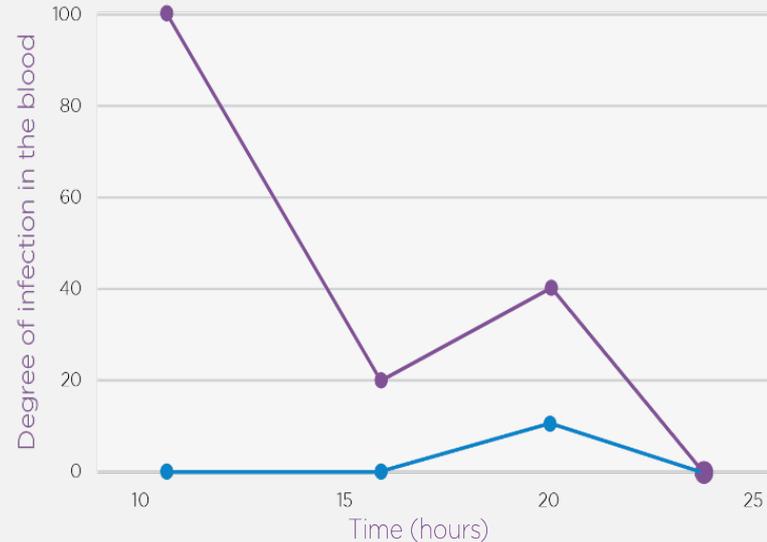
# RECCE® Antibiotics – Curative & Preventative IV Studies\*

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



- ▶ All ten mice treated with RECCE® antibiotic survived
- ▶ Nine mice treated with efficacious dose of Oxacillin (500 mg/kg) survived
- ▶ Four mice that had no treatment at all, survived

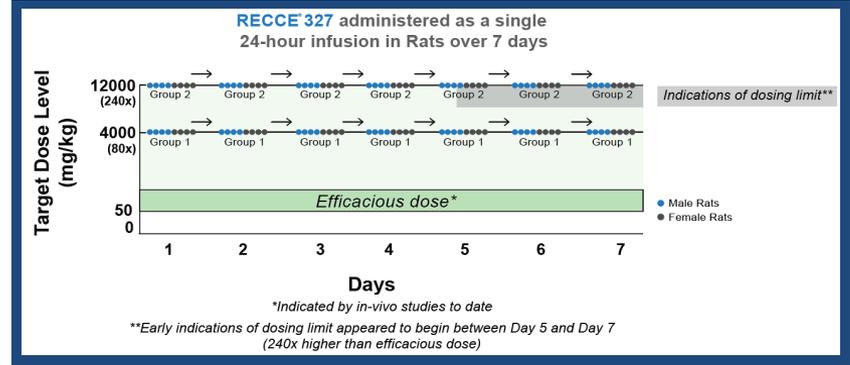
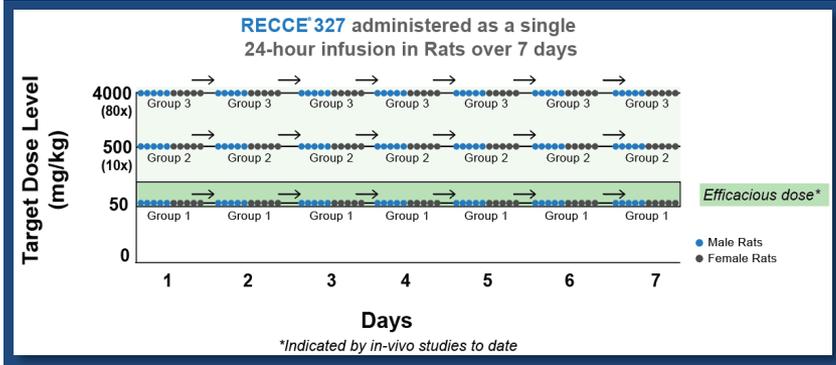
Infection in mice from  
*S. pyogenes*



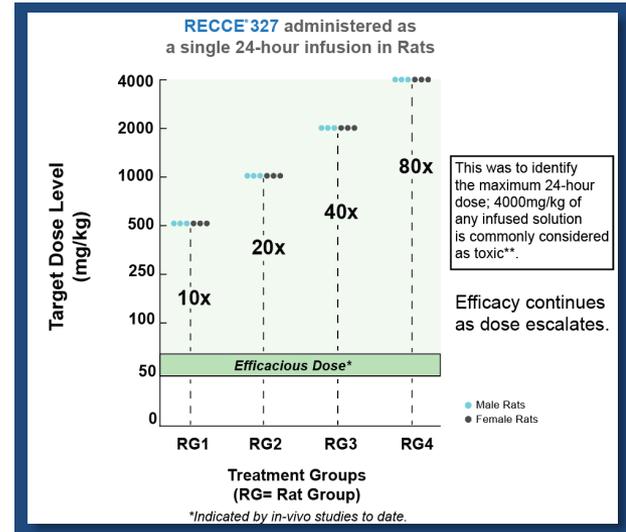
- ▶ **One group of ten mice** were administered a 167 mg/kg dose of RECCE® 327 at 0 hours. **Second group** received no antibiotic.
- ▶ Both groups inoculated with the *S. pyogenes* burden into the bloodstream.
- ▶ Mice results first monitored after 12 hours allowing bacteria to develop and establish an infection.
- ▶ Bacteria in the blood were rapidly killed and unable to establish an infection in the kidneys of mice who received RECCE® 327.

\* Results from an independent laboratory in USA

# Single Dose and Range-Finding Repeat Dosing - Rats

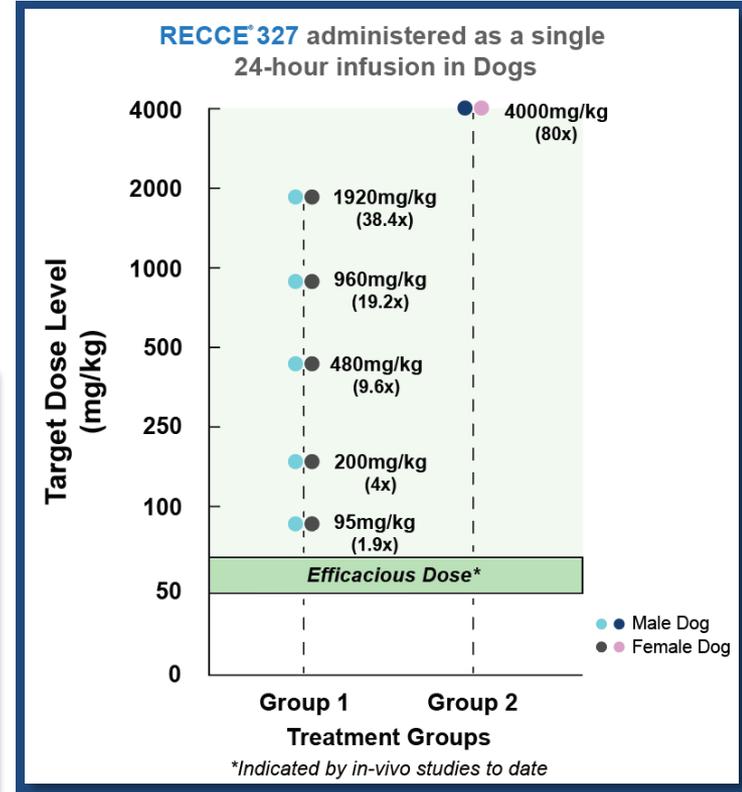
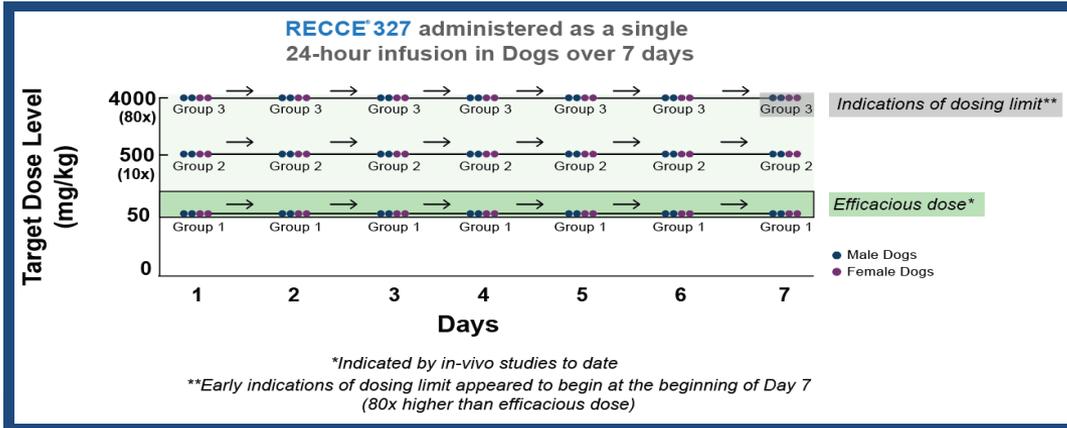


- ▶ **No Observed Adverse Effect Level (NOAEL) of 24-hour 500mg/kg (10x indicated efficacious dose)**
- ▶ Phase Ia (24-hour), Phase Ib (24-hour over 7 days)
  - ▶ A separate single 24-hour intravenous infusion administration of RECCE® 327 up to 12,000 mg/kg over the course of 7-days was carried out.
  - ▶ Results of up 12,000 mg/kg/day was well tolerated from Days 1 to 4 (inclusive); with no mortalities or clinical signs.
  - ▶ 24-hour dosing up to 4,000 mg/kg (80x indicated efficacious dose) in Dogs well tolerated.
  - ▶ RECCE® 327 is indicated to be efficacious from as little as 50mg/kg and here shows tolerability can be sustained over at least 7 days of continuous daily exposure at doses up to and including 500 mg/kg.

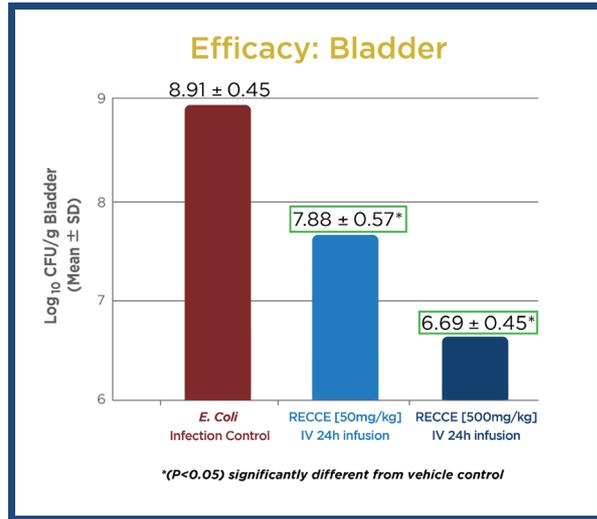


# Single Dose and Range-Finding Repeat Dosing - Dogs

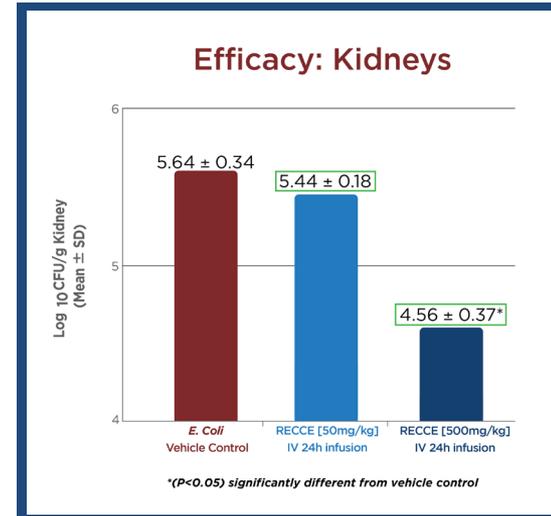
- ▶ **No Observed Adverse Effect Level (NOAEL) of 24-hour 500mg/kg (10x indicated efficacious dose)**
- ▶ Phase Ia (24-hour), Phase Ib (24-hour over 7 days)
- ▶ A single 24-hour intravenous infusion administration of RECCE® 327 up to 4000 mg/kg and 7-day continuous intravenous infusion administration of RECCE® 327 up to 500 mg/kg/day were well tolerated; with no mortalities, clinical signs, changes in body weight, coagulation, clinical chemistry or salient macroscopic abnormalities.
- ▶ RECCE® 327 is indicated to be efficacious from as little as 50mg/kg
- ▶ Therapeutic dose window appears considerably wider than Vancomycin and other antibiotics.



# Pre-sepsis UTI and Kidney Models in Mice



- Group 1 – Bladder *E. Coli* infection + vehicle control
- Group 2 – Bladder *E. Coli* infection + RECCE<sup>®</sup> 327 50mg/kg
- Group 3 – Bladder *E. Coli* infection + RECCE<sup>®</sup> 327 500mg/kg

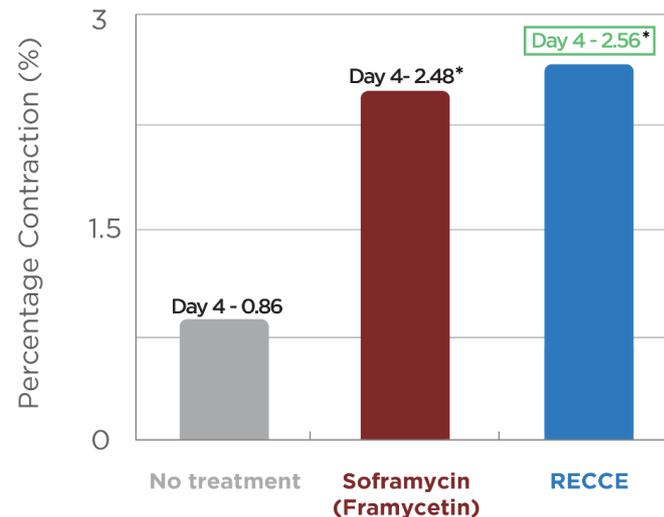
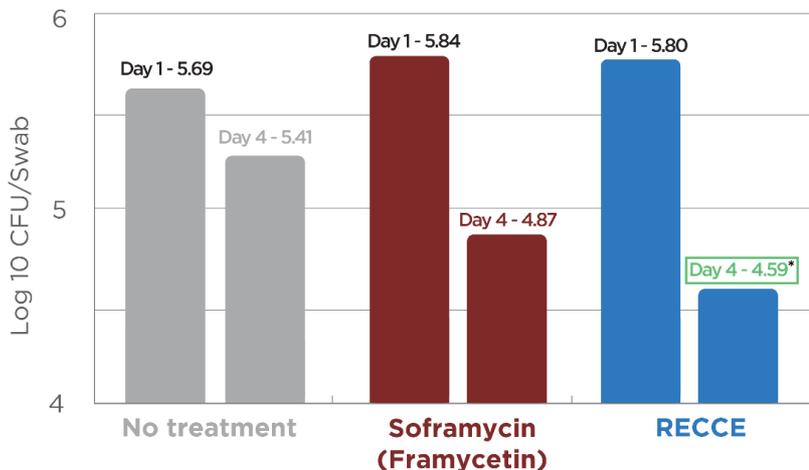


- Group 1 – Kidney *E. Coli* infection + vehicle control
- Group 2 – Kidney *E. Coli* infection + RECCE<sup>®</sup> 327 50mg/kg
- Group 3 – Kidney *E. Coli* infection + RECCE<sup>®</sup> 327 500mg/kg

- ▶ Single 24-hour intravenous infusion
- ▶ RECCE<sup>®</sup> 327 showed dose dependent antibacterial effect in the kidney and bladder at 50mg/kg and 500mg/kg when compared to vehicle control (p<0.050)
- ▶ Rats treated with RECCE<sup>®</sup> 327 were observed for any adverse clinical signs remained apparently normal throughout the study

# Topical Efficacy – Wound Infection & Contraction

## Superbug Methicillin-Resistant *S. aureus* (MRSA)



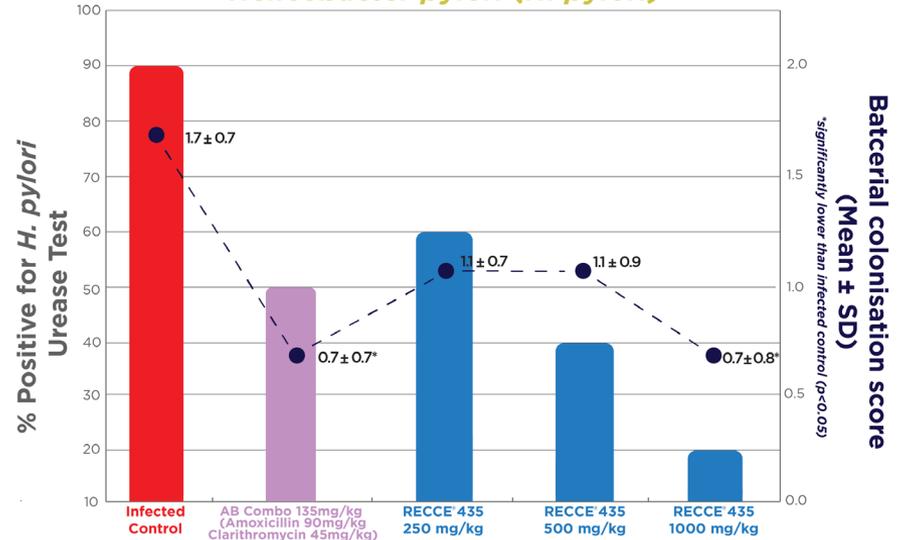
The Study Director noted: “**RECCE® 327** (100 µl (19.15 mg/ml), topical, once daily, over three days), and **Soframycin** (30 mg, topical, twice daily, Q=12hr, over three days) **showed a significant reduction wound on day four** ( $p<0.05$ ) when compared to day one, when compared to the vehicle control.”

The Study Director noted: “**RECCE® 327** (100 µl (19.15 mg/ml), topical, once daily over three days) **showed significant reduction in bacterial load on day four** when compared to day one. **Soframycin** (30 mg, topical, twice daily, Q=12hr, over three days), **the current standard of care antibiotic did not show significant efficacy on day four...**”

# RECCE® 435 Efficacy Against *H. pylori*

- ▶ New **RECCE® 435** oral showed dose-dependent and significant efficacy against *Helicobacter pylori* (*H. pylori*) bacteria
- ▶ Bacteria isolated from a patient with a duodenal ulcer compared to control vehicle in independent study model in rats
- ▶ Five groups of 10 rats each were observed. Three groups were treated with varying doses of RECCE® 435 (250, 500, 1,000 mg/kg)
  - ▶ **Dose-dependent efficacy was seen at all doses with significant reduction in bacterial load.**
- ▶ High solubility and antibacterial effect supportive of a ‘targeted’ oral therapy for stomach infection
- ▶ Study assessed a combination of two broad spectrum antibiotics being used – Amoxicillin and Clarithromycin.

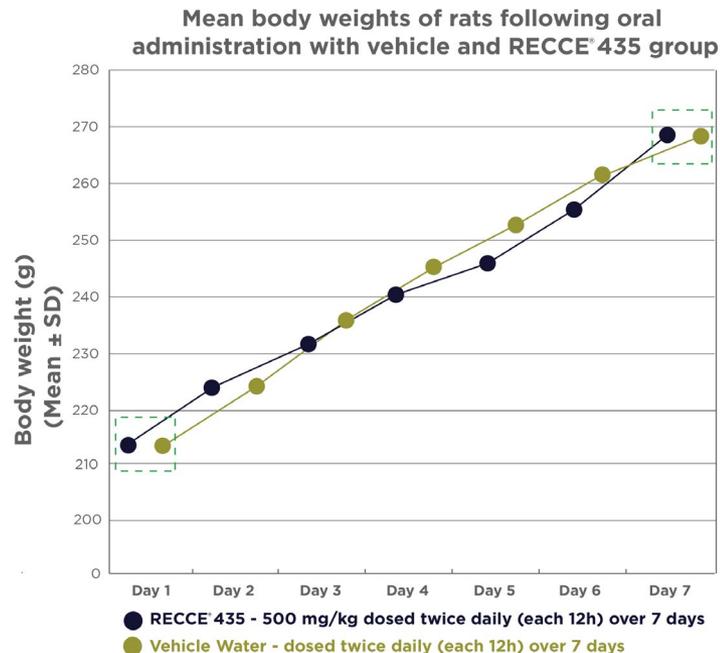
## RECCE® 435 Oral Rat Study *Helicobacter pylori* (*H. pylori*)



Group	Group ID	Rats	Urease test		% Positive for <i>H. pylori</i> [Urease Test]
			Positive	Negative	
1	Uninfected control	10	0	10	0
2	Infected control	10	9	1	90
3	AB Combo 135 mg/kg (Amoxicillin 90 mg/kg + Clarithromycin 45 mg/kg)	10	5	5	50
4	Infected + RECCE® 435 - 250 mg/kg	10	6	4	60
5	Infected + RECCE® 435 - 500 mg/kg	10	4	6	40
6	Infected + RECCE® 435 - 1000 mg/kg	10	2	8	20

# RECCE<sup>®</sup> 435 Efficacy Against *H. pylori*

- ▶ Additional independent study was undertaken
- ▶ Purpose of the study examined the **safety oral dosing** of RECCE<sup>®</sup> 435 up to 500 mg/kg
- ▶ Compound was administered to groups of five mice each twice daily for seven days compared to water-only administration
- ▶ Data indicates their feeding habits, which contributes to weight gain
  - ▶ No negative impact
  - ▶ Supports overall general and gastrointestinal health



Mean body weights of rats following oral administration with vehicle and RECCE <sup>®</sup> 435 group				Body weight (g) (Mean ± SD)			
Days	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Vehicle Water – dosed twice daily (each 12h) over 7 days	213 ± 8.09	224.4 ± 6.73	236.2 ± 4.82	246 ± 5.15	253.2 ± 4.15	262.6 ± 3.65	268.2 ± 5.81
RECCE <sup>®</sup> 435 - 500 mg/kg dosed twice daily (each 12h) over 7 days	213.4 ± 4.56	223.4 ± 9.32	231.6 ± 7.7	240 ± 4.74	246.8 ± 5.89	255.2 ± 9.65	269.4 ± 5.77

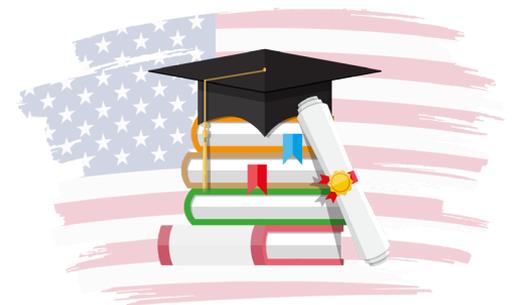
# SARS-CoV-2 Antiviral Program

- ▶ **RECCE® 327** compound selected as **Priority 1** candidate group for testing in SARS-CoV-2 Antiviral Program.
- ▶ The program is run by CSIRO and The Peter Doherty Institute for Infection and Immunology.
- ▶ Compounds were chosen by a Science Selection Panel including field experts in the areas of: Virology, Antivirals, Medicinal Chemistry & Clinical Trials of Antiviral drugs.
- ▶ Therapeutic anti-viral treatment focus with added potential benefit against secondary bacterial infections.



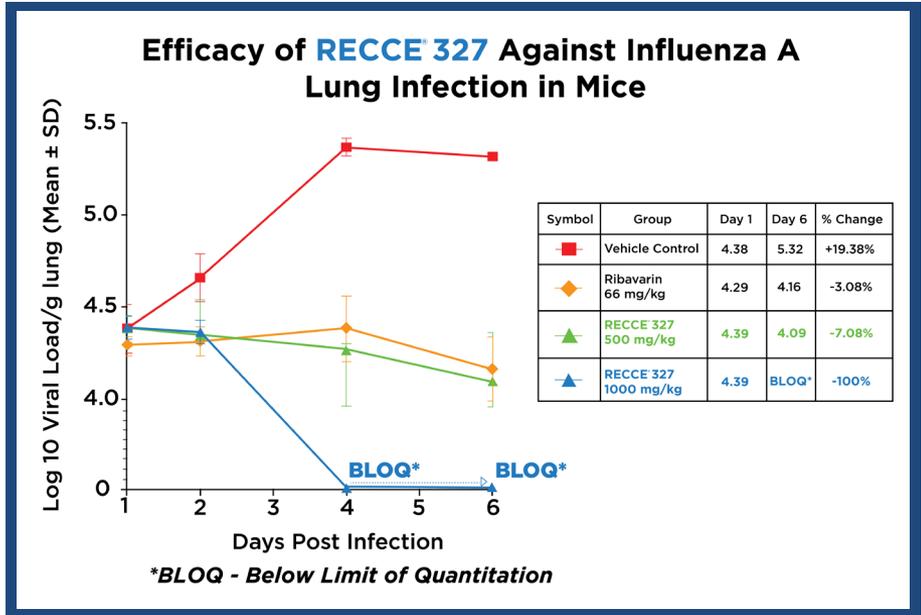
# SARS-CoV-2 International Study

- ▶ **RECCE® 327 and RECCE® 529 to be tested against SARS-CoV-2 in international study**
- ▶ Study led by Path BioAnalytics and conducted in a laboratory at a leading academic institution in the U.S.
- ▶ Purpose of study:
  - ▶ Evaluate **RECCE® 327** and **RECCE® 529** for prevention and/or mitigation of SARS-CoV-2 infections
  - ▶ Study will be conducted as an ex-vivo respiratory organoid model system.
- ▶ Path BioAnalytics is a precision medicine company dedicated to the advancement of next generation treatments for diseases with high unmet need.
- ▶ All intellectual properties are retained by the Company



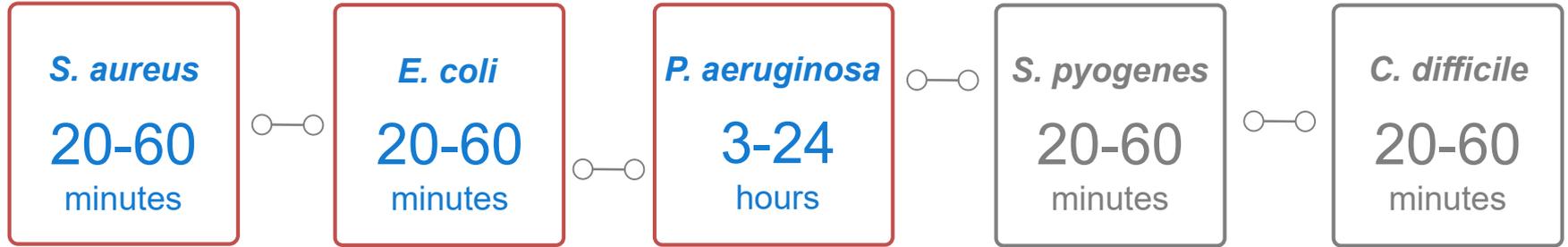
# RECCE<sup>®</sup> 327 Efficacy Against Influenza A

- ▶ Study conducted to assess dose-dependent efficacy of RECCE<sup>®</sup> 327 and *in vivo* anti-viral activity against Influenza A
- ▶ Four groups of 12 mice infected with Influenza A
  - ▶ **Dramatic reduction in viral growth rate and load in the lungs of mice treated with RECCE<sup>®</sup> 327** compared to approved antiviral drug treated and vehicle control untreated groups
  - ▶ **As dosage increased the viral count fell below limit of quantitation (BLOQ) on Days 4 and 6 post infection**
- ▶ Genome of Influenza A virus similar to that of Coronaviruses – both genomes being single-stranded ribonucleic acid molecules
- ▶ **Company is moving quickly to assess RECCE<sup>®</sup> 327 in other major viral infections**

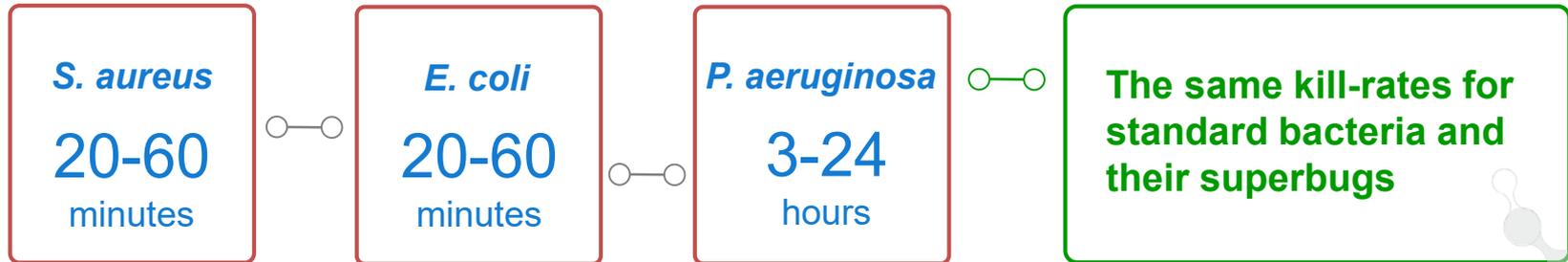


# RECCE<sup>®</sup> 327 kills at practical speeds

## Rates of kill of standard bacteria



## Rates of kill of Superbugs



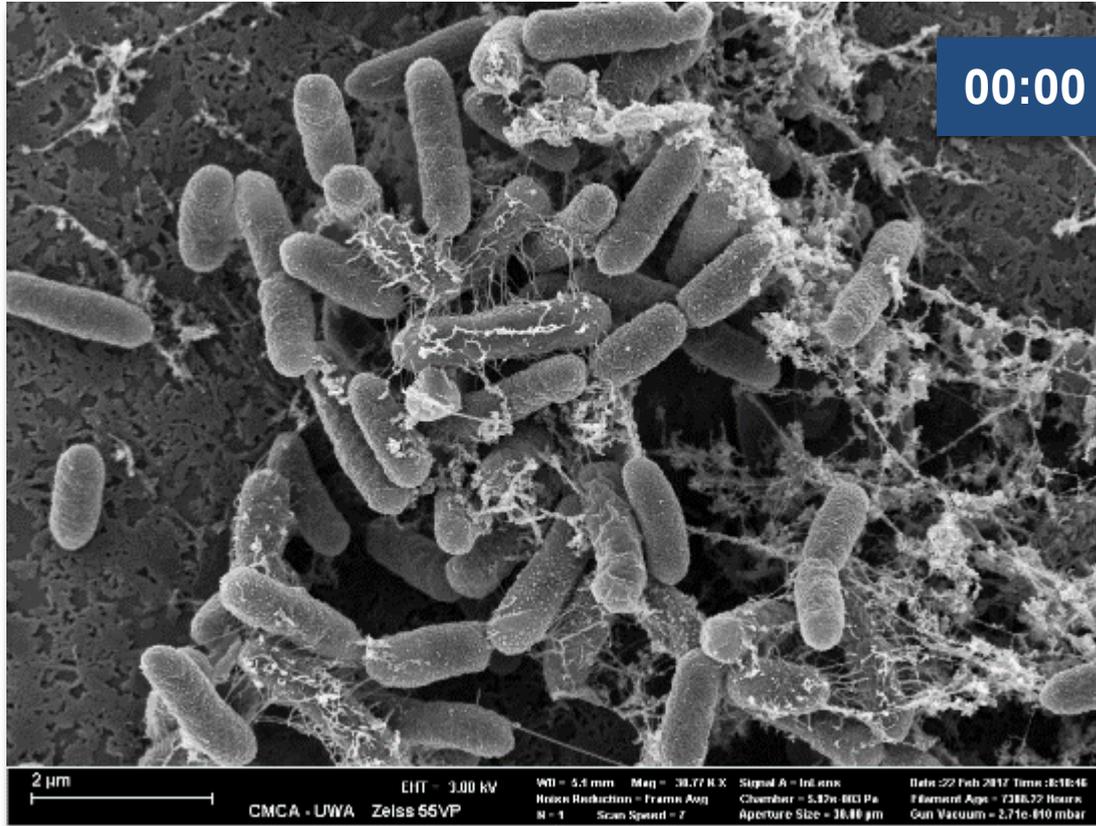
# RECCE<sup>®</sup> 327 Does Not Lose Activity!<sup>1</sup>

Number of repetitive uses before displaying loss of antibiotic activity

Bacteria	Commercial Antibiotic	RECCE <sup>®</sup> Antibiotic
 <i>S. aureus</i>	8 Repeats	>25 Repeats
 <i>E. coli</i>	2 Repeats	
 <i>P. aeruginosa</i>	6 Repeats	

<sup>1</sup> After repetitive use, the commercial antibiotic loses activity; >25 repeats **RECCE<sup>®</sup> 327 DOES NOT**

# RECCE® 327 Mechanism of Action in practice



00:00 minutes

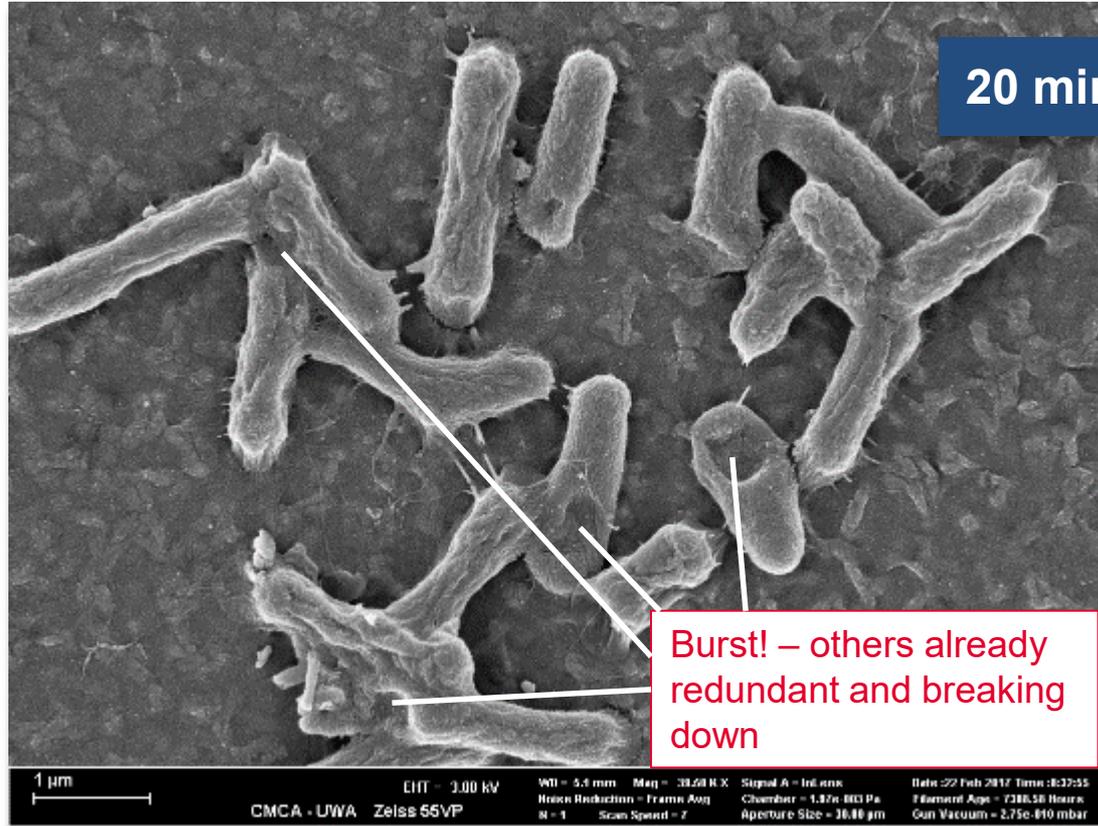
Before application of RECCE® 327, the *E.coli* bacteria cells are healthy, smooth and intact

## *E.coli* Facts<sup>1</sup>

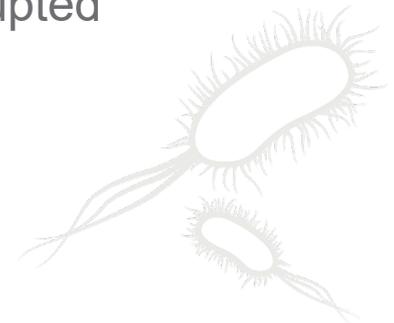
- Part of the Enterobacteriaceae family
- **\$1.2bn USD** estimated attributable healthcare costs in 2017
- CDC labels this bacteria as a **Serious Threat**
- **50% increase** in cases since 2012

<sup>1</sup>CDC Antibiotic Resistance Report 2019

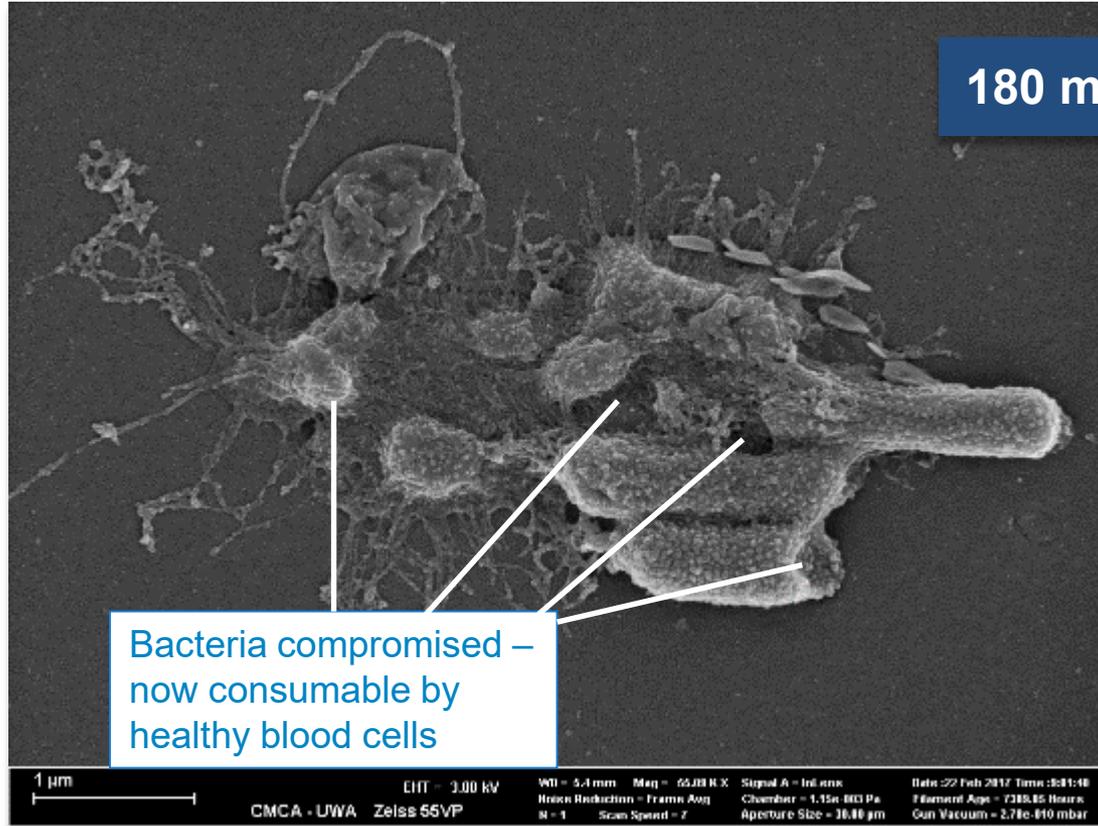
# RECCE<sup>®</sup> 327 Mechanism of Action in practice



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



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

# Patents and trademarks

Recce's patent portfolio includes more than 15 issued patents and patent applications in the world's major markets, including the United States, Europe, Japan, China and Australia.

## Patent Family 1 – Antimicrobial Polymers and Their Compositions

- ▶ Family 1 group relates to the Company's unique and highly economical manufacturing process and use of the polymer in treatment of diseases

## Patent Family 2 – Copolymer for use in Method of Treatment of a Parenteral Infection

- ▶ Family 2 relates to the method of manufacture, administration and application to treat a broad range of common human infections.

## Patent Family 3 – Anti-Virus Agent and Method for Treatment of Viral Infection

- ▶ Family 3 relates to a method of treatment of a broad range of viral infections, particularly parenteral viral infection

Filed	Patent Family 1 Granted	Expiry	Patent Family 2	Expiry	Patent Family 3	Expiry	Patent Family 4	Trademarks registered
Australia	✓	2028	✓	2035	Pending	2035	Pending	✓
USA	✓	2029	✓	2035	Pending	2035	Pending	✓
Europe	✓	2028	✓	2035	Pending	2035	Pending	✓
Germany	✓	2028	✓	2035	Pending	2035	Pending	-
Spain	✓	2028	✓	2035	Pending	2035	Pending	-
France	✓	2029	✓	2035	Pending	2035	Pending	-
United Kingdom	✓	2028	✓	2035	Pending	2035	Pending	-
Italy	✓	2028	✓	2035	Pending	2035	Pending	-
Sweden	✓	2028	✓	2035	Pending	2035	Pending	-
Japan	✓	2028	✓	2035	Pending	2035	Pending	✓
China	✓	2028	Pending	2035	Pending	2035	Pending	✓

# 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'

# Investment summary



R327 Qualified Infectious Disease Product (QIDP) Designation



R327 Generating Antibiotics Incentive Now (GAIN) Act approved



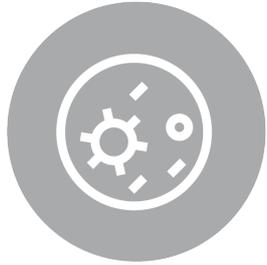
Proprietary technology as a new class of synthetic anti-infectives



R327 addressing the most expensive condition faced by hospitals worldwide



Early commercialisation potential



R327 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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