



Corporate Presentation

ASX:RCE

Switzer

SMALL AND MICRO CAP
Virtual Investor Day 2020

James Graham
CEO

30 Oct. 2020
12.15pm – 12.30pm

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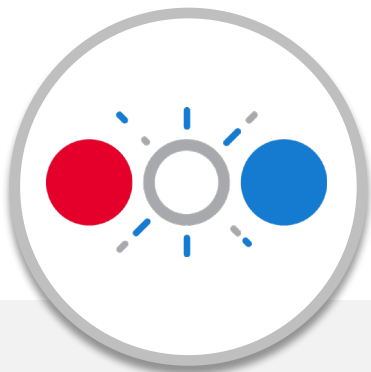
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About Recce Pharmaceuticals Ltd

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)

Unique and universal
Mechanism of Action

Water soluble over a broad
range of pH levels



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

RECCE® 327 & RECCE® 435 –
bacterial indications

RECCE® 529 –
viral indications



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 – 28 October 2020

G & O Melrose*	23.6%
LDU Pty Ltd	4.3%
HSBC Nominees	3.6%
J Graham**	3.5%
JP Morgan Nominees	2.9%
Acuity Capital	2.6%
M Dilizia**	2.1%

ASX:RCE 6 months



Snapshot

ASX code	RCE
Shares on issue 27 October 2020	173.63 million
Share price 27 October 2020	AUD \$0.94 cents
Market Cap (approx.) 27 October 2020	AUD \$163.2 million
Cash and deposits 30 September 2020	AUD \$25.7 million
Trading range 52 week	AUD 0.21c - \$1.875
Average daily volume 3 months	547.86K
Debt	Nil

Recce Pharmaceuticals Ltd – Major Shareholders

Major Shareholders	As of 30 Sept. 2020	As of 28 Oct. 2020	Change in Holding
G & O Melrose*	23.6%	23.6%	No change
LDU Pty Ltd	4.2%	4.3%	Increased holding
HSBC Nominees	3.8%	3.6%	Minor change
J Graham**	3.5%	3.5%	No change
JP Morgan Nominees	2.6%	2.9%	Increased holding
Acuity Capital	2.6%	2.6%	No change
M Dilizia**	2.1%	2.1%	No change
Acewood Investments	1.8%	1.8%	No change
Citicorp Nominees	1.6%	1.2%	Minor change
CS Third Nominees***	1.1%	0.3%	Minor change
Querion Pty Ltd	1.2%	1.2%	No change
Golden Rivers Mining	0.66%	0.66%	No change
N & S Shirobokov	0.61%	0.61%	No change
R & Z Cerny	0.58%	0.58%	No change
Shortis Natural Therapies	0.58%	0.58%	No change
McCray Investments Pty Ltd	0.53%	0.56%	Increased holding
Pejay Pty Ltd	0.53%	0.56%	Increased holding
L & E Field	0.54%	0.54%	No change
M Swinn	0.48%	0.48%	No change
C & P Frisch	0.45%	0.46%	Increased holding
D Pyman	0.39%	0.40%	Increased holding
Super and Investment Holdings	0.36%	0.36%	No change
Total	53.81%	52.89%	- 0.92% change



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

James Graham – Managing Director & Chief Executive Officer

BCom (Entrepreneurship), GAICD

5 years as former Executive Director

Invested along-side shareholders in most capital rounds since inception.

Background in marketing, business development and commercialisation of early stage technologies.

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.

Michele Dilizia – Executive Director & Chief Scientific Officer

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

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

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 & Head of Manufacturing

BSc Eng (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.

Professor Philip Sutton – Head of *H. pylori* Development Program

Global infectious disease expert with over 30 years of research and industry experience, having served as former Head of Immunology at CSL Ltd in Melbourne. Chief Editor of textbook "*Helicobacter pylori* in the 21st Century" and has co-authored 92 manuscripts published in peer-reviewed journals. Professor Sutton currently leads Mucosal Immunology Group at Murdoch Children's Research Institute.

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 subjects to be screened in Q4 2020

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

Topical Administration

Phase I/II topical study HREC approved

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

Viral Indications

R327 dispatched to CSIRO, R327 & R529 dispatched to Path BioAnalytics

- ▶ Influenza A and other significant respiratory infections
- ▶ R327 Priority 1 Candidate Group - SARS-CoV-2 Anti-viral 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 R435 to be tested against *H. pylori* with Murdoch Children's Research Institute

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



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!

Sepsis – it's a big problem!

48.9 million incident cases of sepsis
recorded worldwide¹

11 million sepsis related deaths recorded²

One in three patients
who **die** in hospital
have sepsis³



- ▶ 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.⁴
- ▶ Has been the **most expensive condition to treat** in the last 8 years - **double the average cost per stay across all other conditions**.⁵
- ▶ **Currently no drug therapies specifically for the treatment of sepsis.**⁶

1,2,3 – The Lancet

4 – BioMed Central

5 – University of Texas

6 – International Medicine Journal RACP

RECCE® 327 Phase I Human Clinical Trial

- ▶ **Human safety and tolerability study to assess IV infusion of RECCE® 327 in 48 healthy subjects as a single ascending dose**
- ▶ Phase I trial agreement with leading clinical research organization PAREXEL
- ▶ Trial will be held at CMAX Clinical Research – an independent trial facility
- ▶ **Facility meets international regulatory authority data entry and quality requirements including European Medicines Agency and US FDA**
- ▶ Formal subject recruitment to open for enrolments shortly
 - ▶ CMAX has more than 30,000 registered patient volunteers on file
 - ▶ First patients expected to be screened in Q4 2020



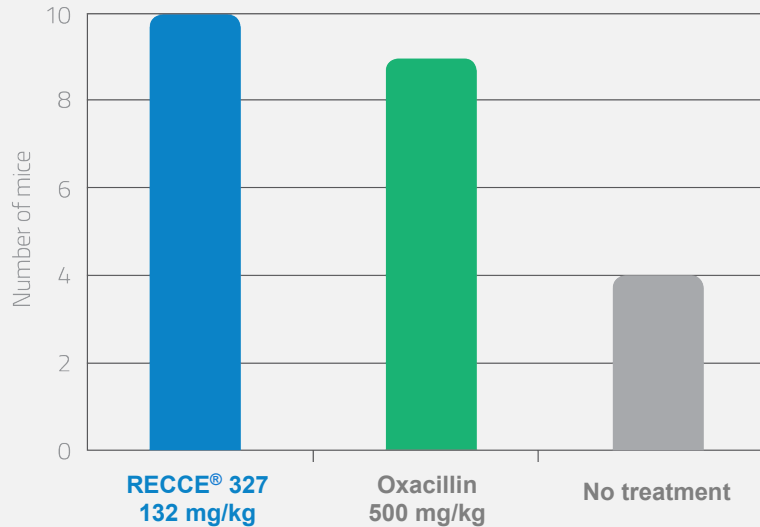
CMAX Nursing station for participant monitoring



CMAX Phase I Clinical Unit

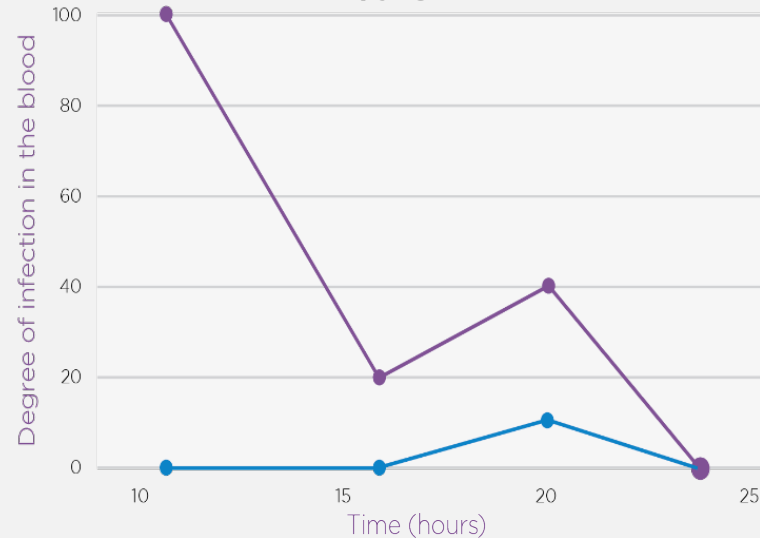
RECCE® Antibiotics – Curative & Preventative IV Studies*

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

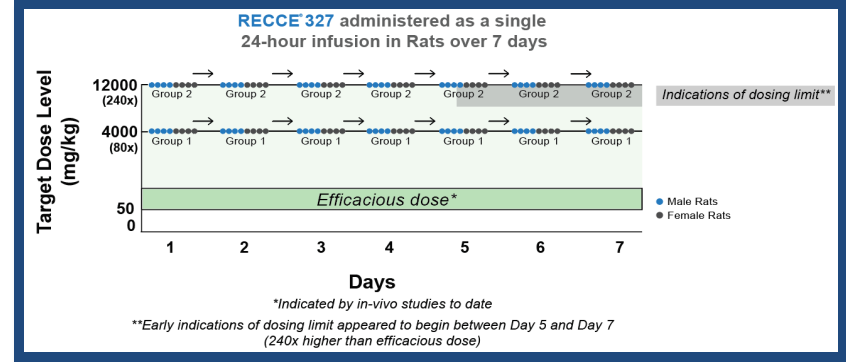
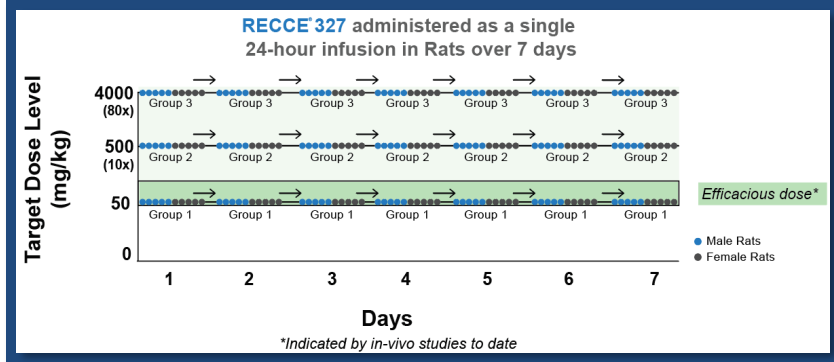
Infection in mice from
S. pyogenes



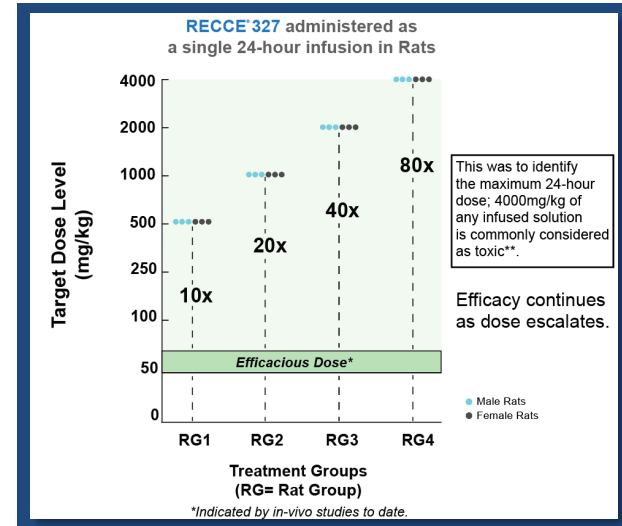
- ▶ **One group of ten mice** were administered a 167 mg/kg dose of RECCE® 327 at 0 hours. **Second group** received no antibiotic.
- ▶ Both groups inoculated with the *S. pyogenes* burden into the bloodstream.
- ▶ Mice results first monitored after 12 hours allowing bacteria to develop and establish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

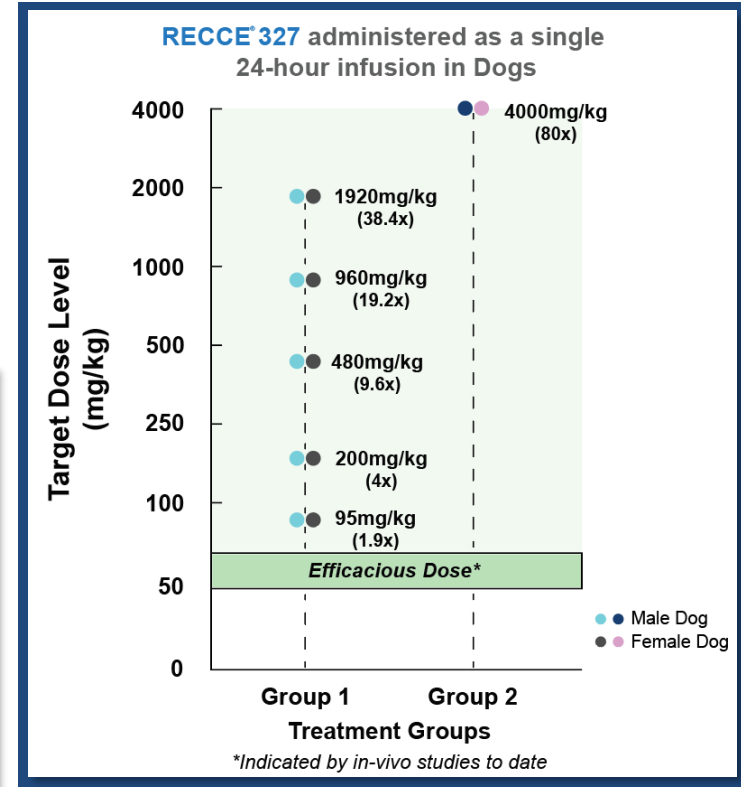
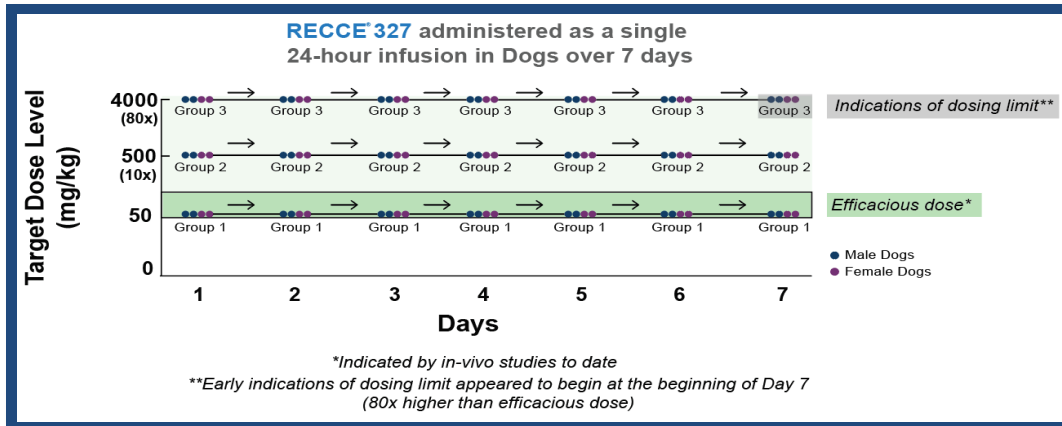


- ▶ **No Observed Adverse Effect Level (NOAEL) of 24-hour 500mg/kg (10x indicated efficacious dose)**
- ▶ Phase Ia (24-hour), Phase Ib (24-hour over 7 days)
 - ▶ A separate single 24-hour intravenous infusion administration of RECCE® 327 up to 12,000 mg/kg over the course of 7-days was carried out.
 - ▶ 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.



RECCE® 327 Phase I/II Topical Human Trial

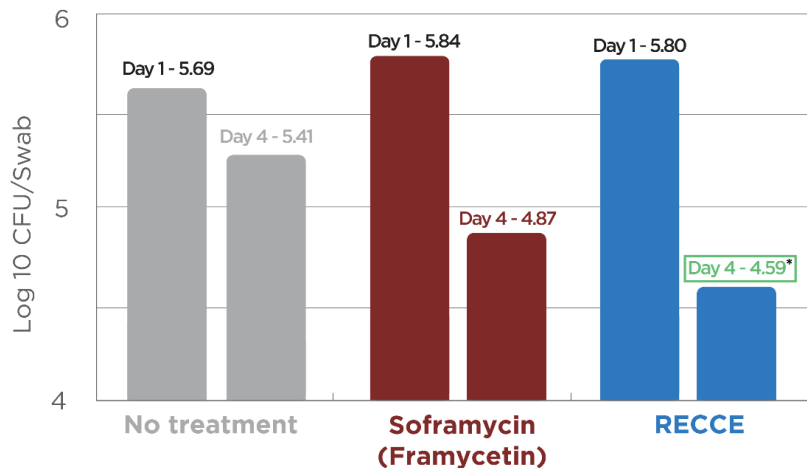
- ▶ The topical study will assess RECCE® 327 as a broad-spectrum antibiotic for patients with Gram-positive and Gram-negative bacterial burn wound infections
- ▶ Sponsored by the South Metropolitan Health Service, Department of Health, Government of Western Australia
 - ▶ **Fiona Stanley Hospital nominated as the study site**
 - ▶ **Principal Investigator Professor Fiona Wood**
 - ▶ **Dr Wood pioneered the innovative the worlds-first 'spray-on skin' technique, which greatly reduces permanent scarring in burns victims.**
- ▶ Over 14 days, 10 patients will receive RECCE® 327 daily while a further 20 receive treatment 3 times per week
- ▶ Phase I/II clinical trial approved by Human Research Ethics Committee



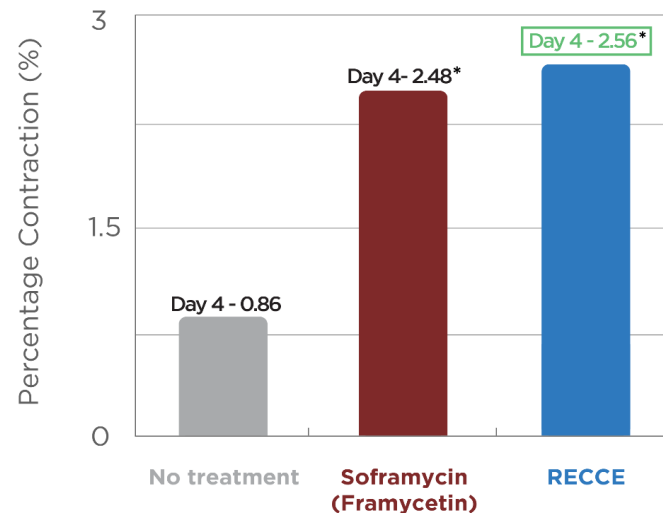
Government of **Western Australia**
South Metropolitan Health Service
Fiona Stanley Hospital

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 Pre-clinical Studies Program

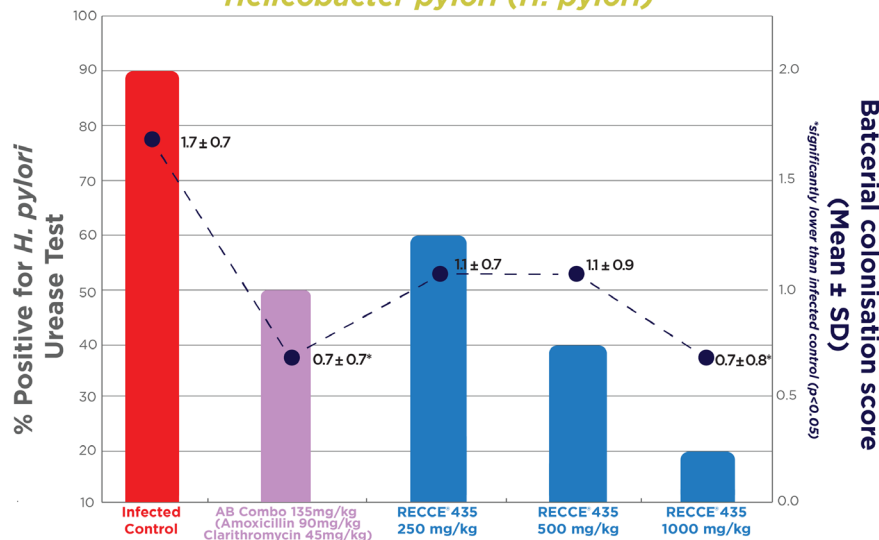
- ▶ Murdoch Children's Research Institute (MCRI) to evaluate *in-vivo* antimicrobial activity of RECCE® 435 oral formulation against *Helicobacter pylori* (*H. pylori*) in pre-clinical studies program
- ▶ RECCE® 435 is a new broad-spectrum synthetic polymer antibiotic formulated for oral use
- ▶ Study led by *H. pylori* infectious disease expert Professor Philip Sutton
- ▶ Research program will be carried out by Mucosal Immunology Group at the MCRI Royal Children's Hospital
 - ▶ MCRI is one of the top three child health research institutes worldwide for research quality and impact
- ▶ Recce and MCRI will work together on the oral antibiotic dosing program with a particular focus on optimal dosing and the effect of RECCE® 435
- ▶ Anticipated completion in approximately 12 months, at which time Recce will pursue a human clinical trial



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.

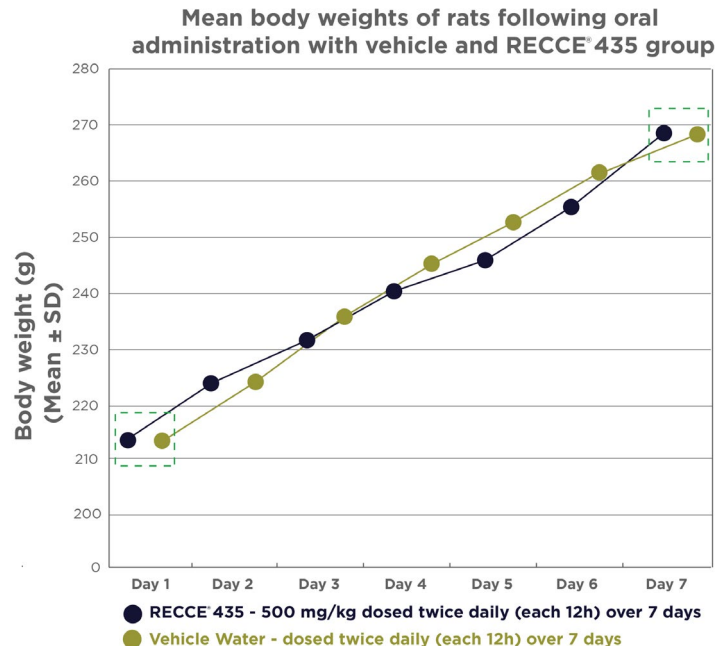
RECCE® 435 Oral Rat Study *Helicobacter pylori* (*H. pylori*)



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® 435 Efficacy Against *H. pylori*

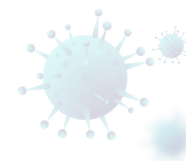
- ▶ Additional independent study was undertaken
- ▶ Purpose of the study examined the **safety oral dosing** of RECCE® 435 up to 500 mg/kg
- ▶ Compound was administered to groups of five mice each twice daily for seven days compared to water-only administration
- ▶ Data indicates their feeding habits, 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® 435 group				Body weight (g) (Mean \pm 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 \pm 8.09	224.4 \pm 6.73	236.2 \pm 4.82	246 \pm 5.15	253.2 \pm 4.15	262.6 \pm 3.65	268.2 \pm 5.81
RECCE® 435 - 500 mg/kg dosed twice daily (each 12h) over 7 days	213.4 \pm 4.56	223.4 \pm 9.32	231.6 \pm 7.7	240 \pm 4.74	246.8 \pm 5.89	255.2 \pm 9.65	269.4 \pm 5.77

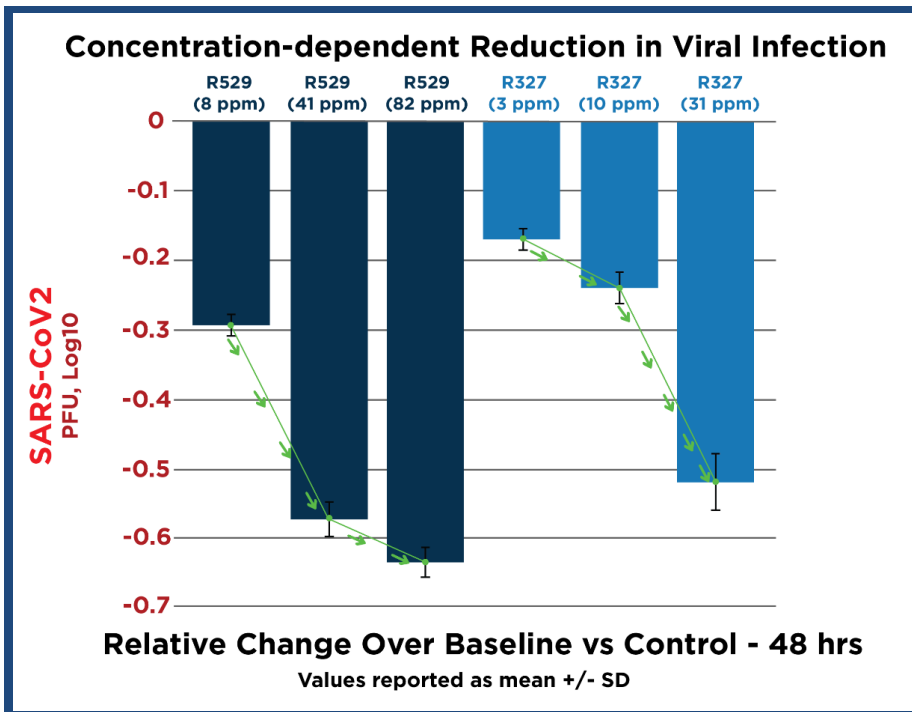
SARS-CoV-2 Antiviral Program

- ▶ **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.
- ▶ All intellectual property rights are retained by the Company



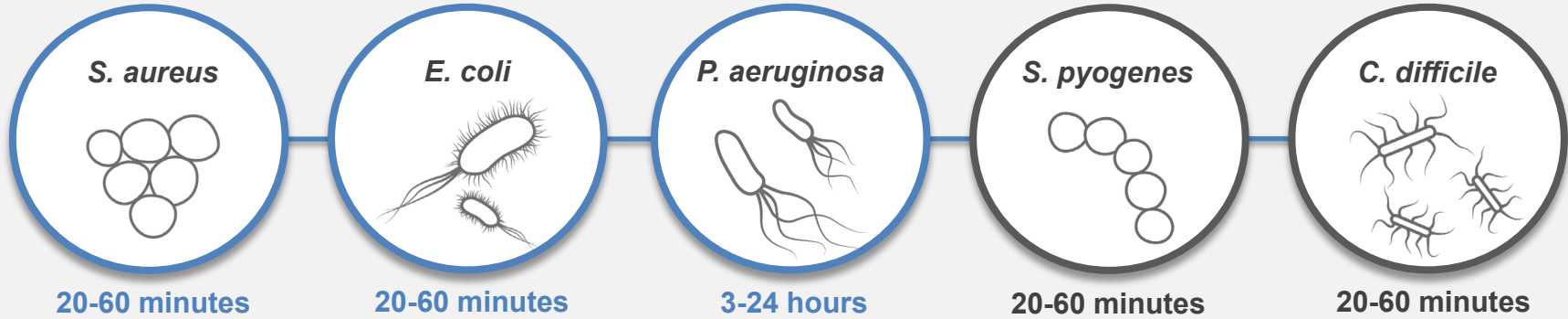
SARS-CoV-2 International Study

- ▶ **RECCE® 327** and **RECCE® 529** have shown concentration-dependent reductions in the SARS-CoV-2 virus
- ▶ Concentrations of R327 and R529 tested, further indicated an **excellent toxicity profile (<0.25%)** on Vero (monkey) cells, in a separately related study
- ▶ COVID-19 studies will be **advancing** to gold-standard animal in-vivo models (e.g. ferret)
 - ▶ **Method of administration** will be via **intranasal** to target viral infection in the airways/lungs
 - ▶ Ferret international study expected to begin September and be completed prior to end of 2020

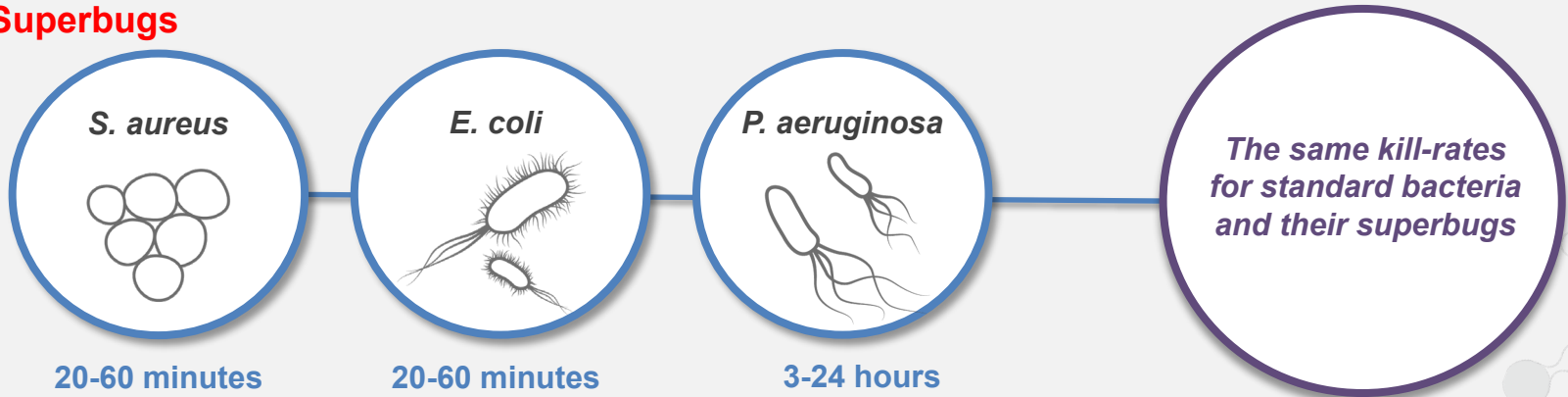


RECCE[®] 327 kills at practical speeds

Standard Bacteria






Superbugs



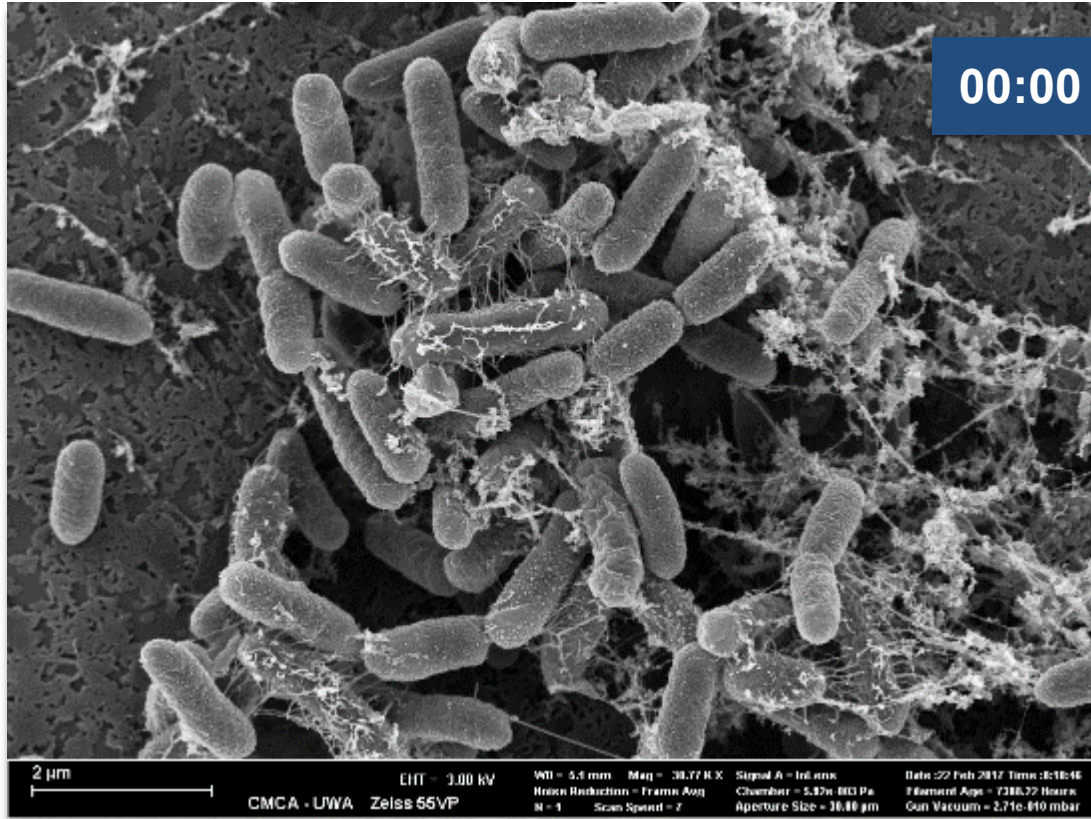
RECCE® 327 Does Not Lose Activity!¹

Number of repetitive uses before displaying loss of antibiotic activity

Bacteria	Commercial Antibiotic	RECCE® 327
 <i>S. aureus</i>	8 Repeats	>25 Repeats
 <i>E. coli</i>	2 Repeats	
 <i>P. aeruginosa</i>	6 Repeats	

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

RECCE® 327 Mechanism of Action in practice



00:00 minutes

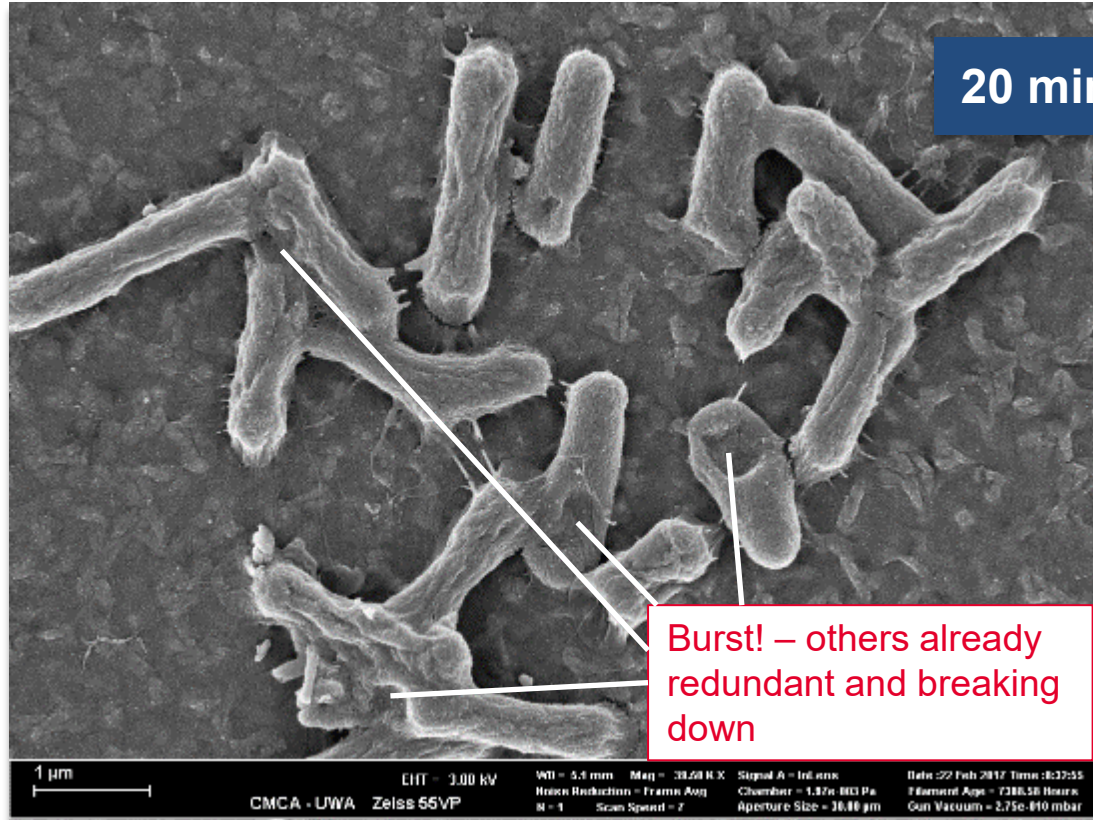
Before application of RECCE® 327, the *E.coli* bacteria cells are healthy, smooth and intact

E.coli Facts¹

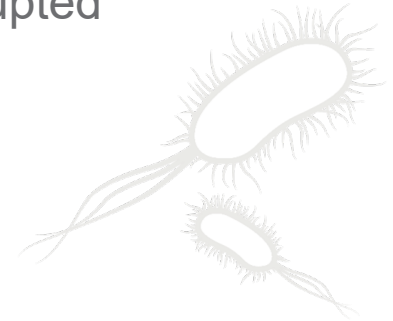
- Part of the Enterobacteriaceae family
- **\$1.2bn USD** estimated attributable healthcare costs in 2017
- CDC labels this bacteria as a **Serious Threat**
- **50% increase** in cases since 2012

¹CDC Antibiotic Resistance Report 2019

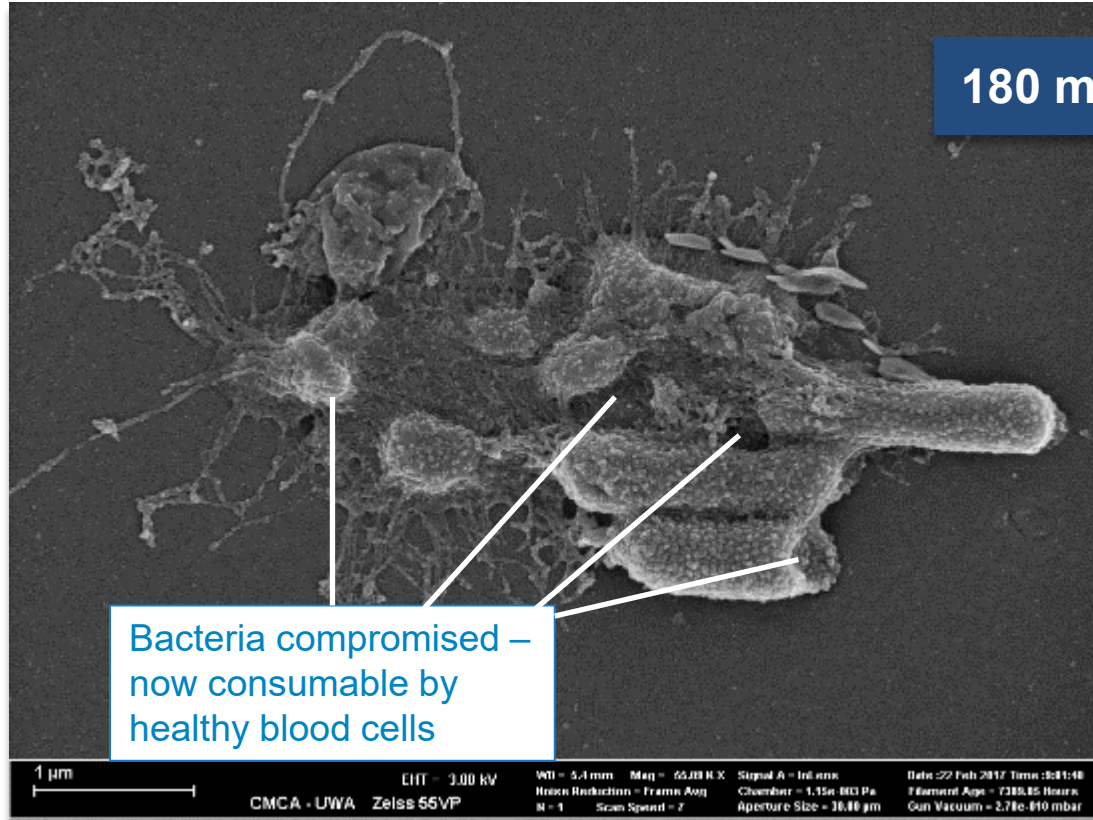
RECCE® 327 Mechanism of Action in practice



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



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)

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 <u>Granted</u>	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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