



***Corporate
Presentation***
ASX:RCE

May 2020

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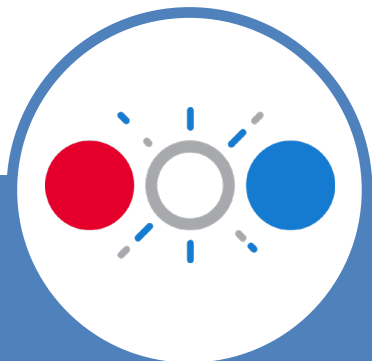
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About Recce Pharmaceuticals Ltd



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.

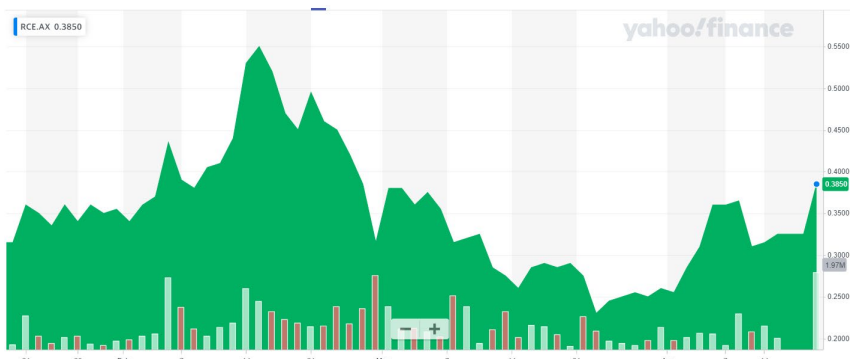


Recce Pharmaceuticals Ltd - Capital structure

Major shareholders* 11 May 2020

1. G. & O. Melrose**	22.5%
2. Vesty Superannuation	4.9%
3. J. Graham**	3.4%
4. Acuity Capital Investment	3.4%
5. JP Morgan Nominees	3.2%

ASX:RCE 3 months



Snapshot

ASX code	RCE
Shares on issue	135.57 million
Share price 14 May 2020	AUD 48 cents
Market Cap (approx.) 14 May 2020	AUD \$65 million
Cash and deposits 31 March 2020	AUD \$4.09 million
Trading range 52 week	AUD 19-59.5 cents
Average daily volume 3 months	550.09K
Debt	Nil

* 28.5% of shares held by Directors

** Held by Executive Directors

RECCE® – Multiple Antibiotic 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

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

Topical Administration

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

Viral Indications

- ▶ Influenza A and other significant respiratory infections

Other Indications

- ▶ 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 I.V infusion of RECCE[®] 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 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 327 in the blood

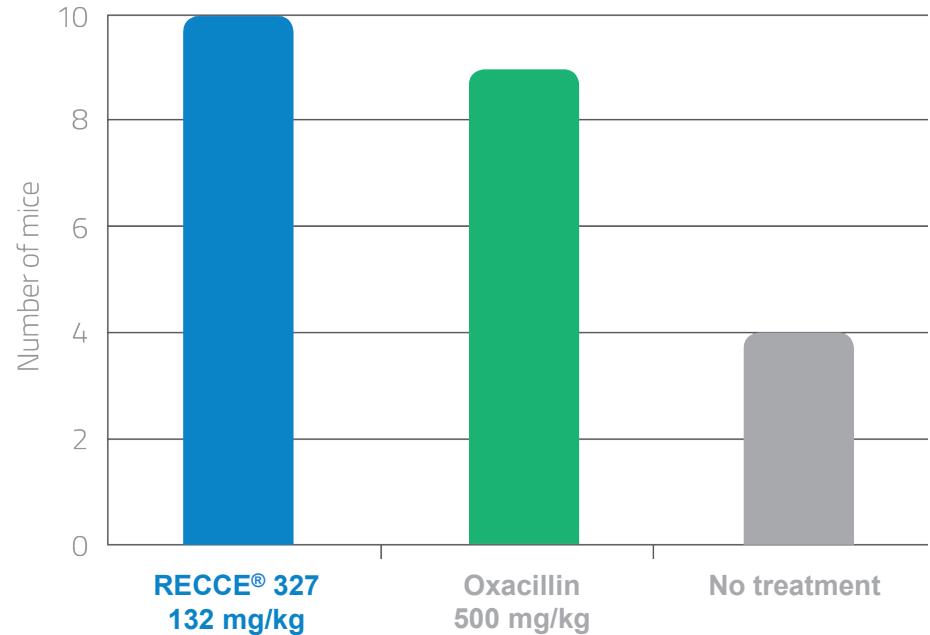
RECCE® Antibiotics – Sepsis IV Curative Study*

- ▶ 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 efficacious dose of Oxacillin (500 mg/kg) survived
- ▶ Four mice that had no treatment at all, survived

Note: Oxacillin is 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)

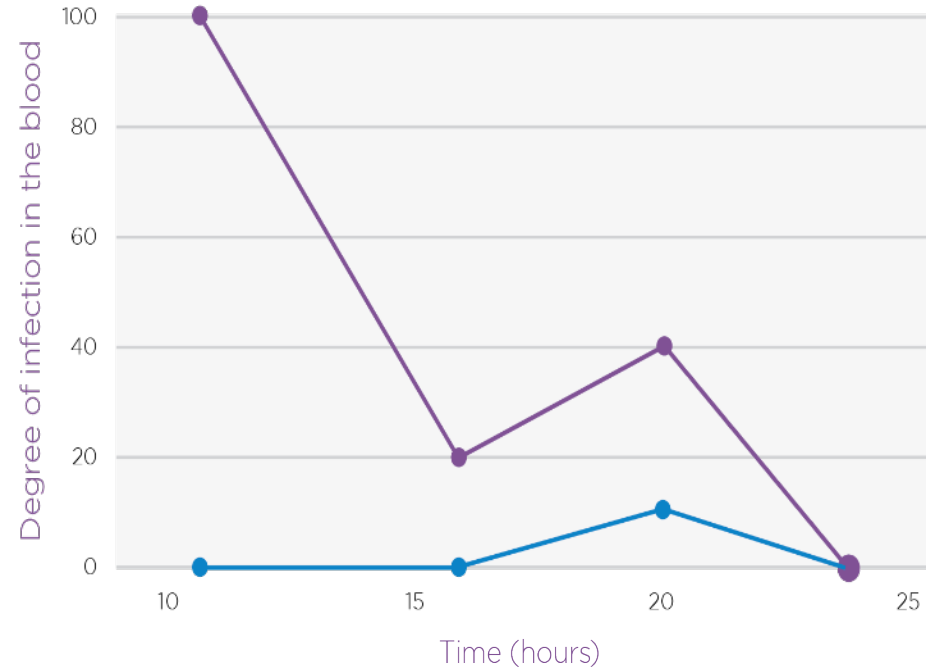


RECCE[®] Antibiotics – Infection IV Preventative Study*

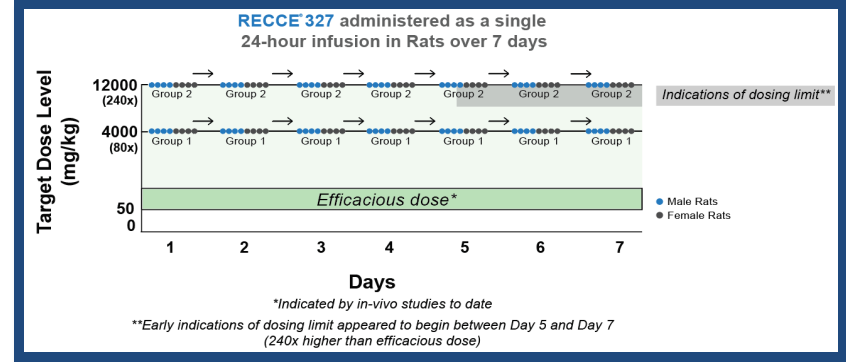
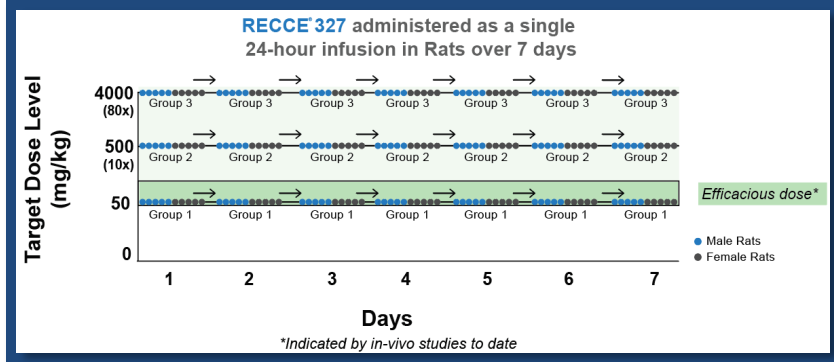
To examine the prophylaxis potential of RECCE[®] 327, a study was carried out using mice that were infected with *S. pyogenes*:

- ▶ **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 were then inoculated with the same *S. pyogenes* burden into the bloodstream.
- ▶ Mice results were first monitored after 12 hours post-inoculation to allow the bacteria enough time 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.
 - ▶ This was attributed to the prophylactic/preventative effect of RECCE[®] 327.
- ▶ The control group's *S. pyogenes* appeared to clear from the blood after 12 hours, **HOWEVER** bacteria rapidly colonise in the kidneys (the blood's natural filter), which commonly leads to catastrophic kidney failure and death.

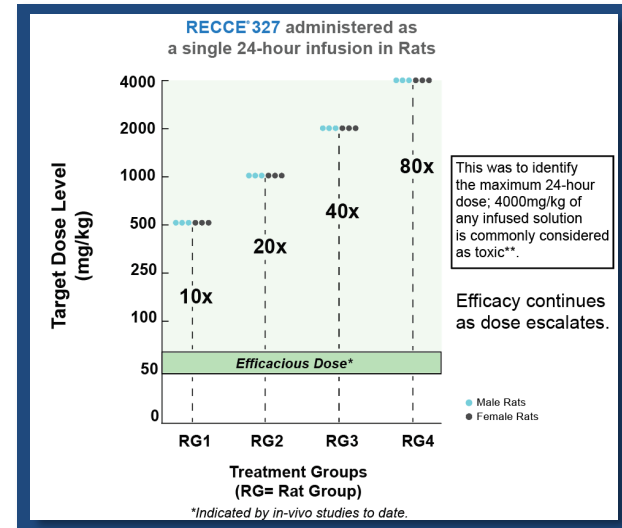
Infection in mice from
Streptococcus pyogenes



Single Dose and Range-Finding Repeat Dosing - Rats

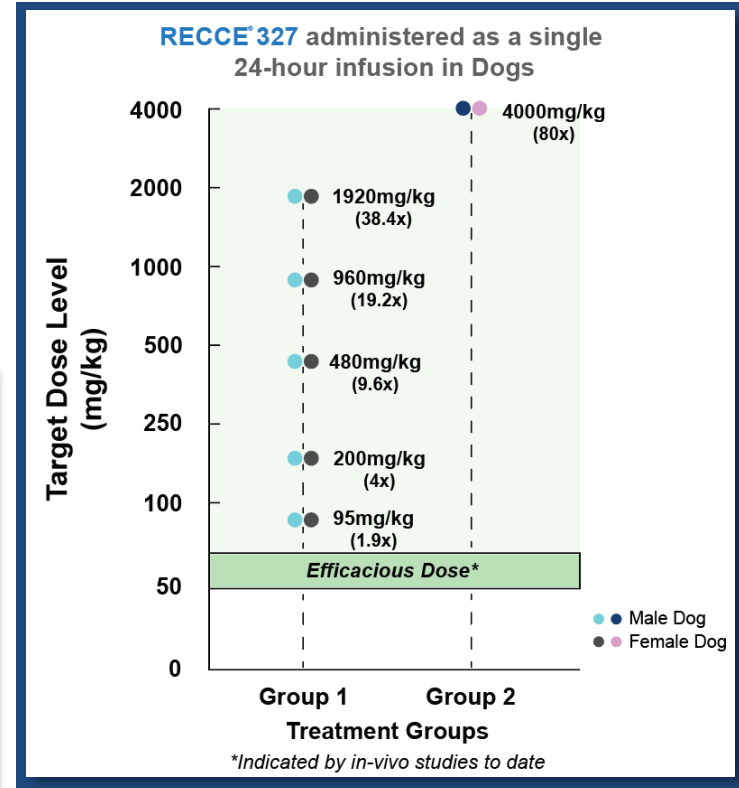
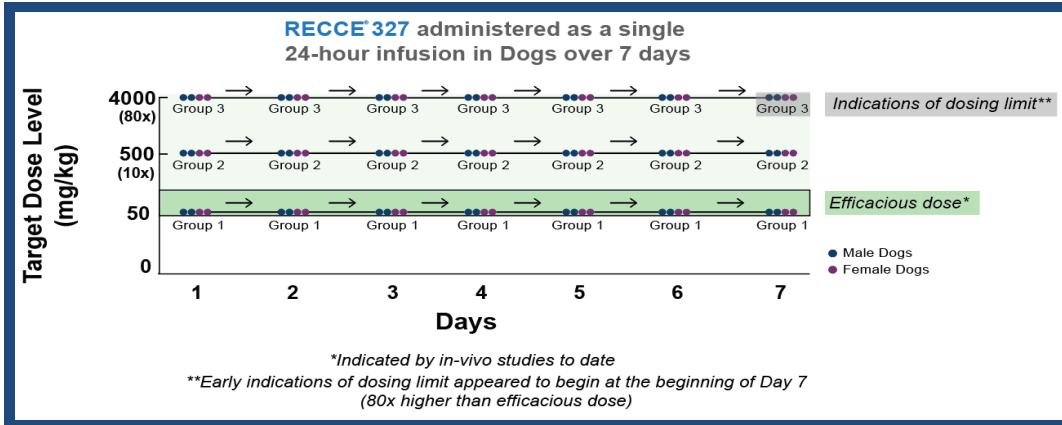


- ▶ **No Observed Adverse Effect Level (NOAEL) of 24-hour 500mg/kg (10x indicated efficacious dose)**
- ▶ Phase Ia (24-hour), Phase Ib (24-hour over 7 days)
 - ▶ A separate single 24-hour intravenous infusion administration of RECCE® 327 up to 12,000 mg/kg over the course of 7-days was carried out.
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

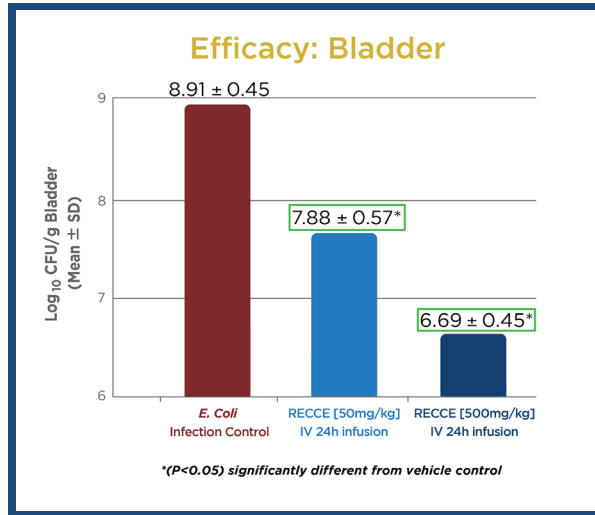


Single Dose and Range-Finding Repeat Dosing - Dogs

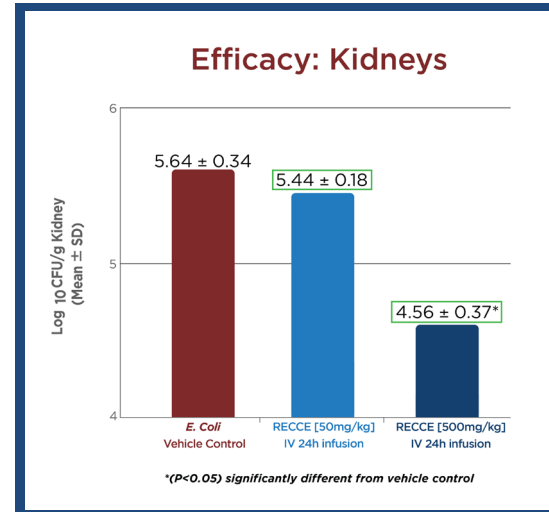
- ▶ **No Observed Adverse Effect Level (NOAEL) of 24-hour 500mg/kg (10x indicated efficacious dose)**
- ▶ Phase Ia (24-hour), Phase Ib (24-hour over 7 days)
- ▶ A single 24-hour intravenous infusion administration of RECCE® 327 up to 4000 mg/kg and 7-day continuous intravenous infusion administration 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® 327 50mg/kg
- Group 3 – Bladder *E. Coli* infection + RECCE® 327 500mg/kg

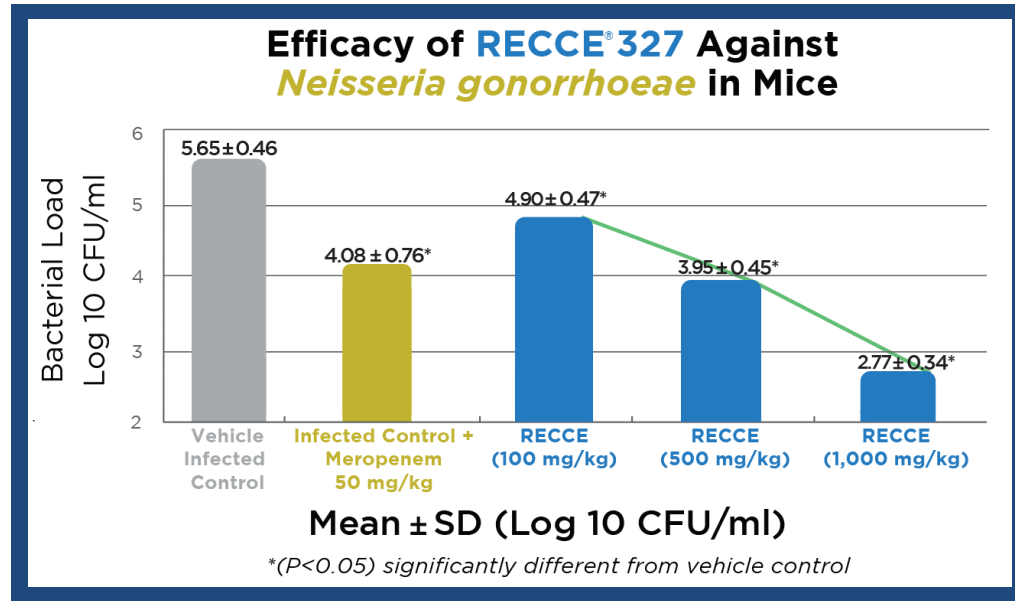


- Group 1 – Kidney *E. Coli* infection + vehicle control
- Group 2 – Kidney *E. Coli* infection + RECCE® 327 50mg/kg
- Group 3 – Kidney *E. Coli* infection + RECCE® 327 500mg/kg

- ▶ Single 24-hour intravenous infusion
- ▶ RECCE® 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® 327 were observed for any adverse clinical signs remained apparently normal throughout the study

RECCE[®] 327 Efficacy Against *Neisseria gonorrhoeae*

- ▶ Statistically significant reduction of *Neisseria gonorrhoeae* in reproductive organs of female mice.
- ▶ RECCE[®] 327 outperformed market approved drug Meropenem in most instances.
- ▶ *Neisseria gonorrhoeae*, a species of Gram-negative bacteria, and the second most common sexually transmitted infection (STI) globally.
- ▶ RECCE[®] 327 showed significant dose dependent antibacterial effect in vaginal load at 100, 500 and 1000 mg/kg given by IV bolus
- ▶ Meropenem's high rates of bacterial resistance have recently led to restriction of its use strictly reserved for infections caused by resistant organisms.
- ▶ Potential of RECCE[®] 327 to not only become a potent broad-spectrum antibiotic but most critically to continue working against antibiotic resistant bacteria or superbugs, even with repeated use

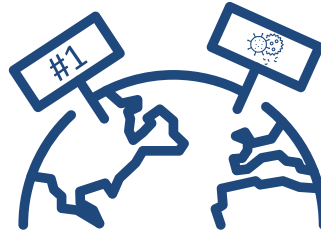


Skin & Soft Tissue Infections (SSTIs) – Methicillin Resistant *Staphylococcus aureus* (MRSA)

SSTIs account for
3.4 million ED* visits in the US¹



MRSA leading cause of
wound infections globally²



MRSA attributing to **AU\$2.5bn**
to healthcare costs in US³



- ▶ The incidence of *Staphylococcus aureus* **SSTIs doubled in 8 years**⁴
 - The CDC report **327.7K cases of MRSA in hospitalized patients in the United States**⁵
- ▶ The burden of SSTIs and their complications are considerable resulting in:⁶
 - ▶ Hospitalization
 - ▶ Surgery
 - ▶ Bacteremia (**Sepsis**)
 - ▶ **Death**
- ▶ In the emergency care setting, **SSTIs represent the third most common diagnosis after chest pain and asthma**⁷

*Emergency Department

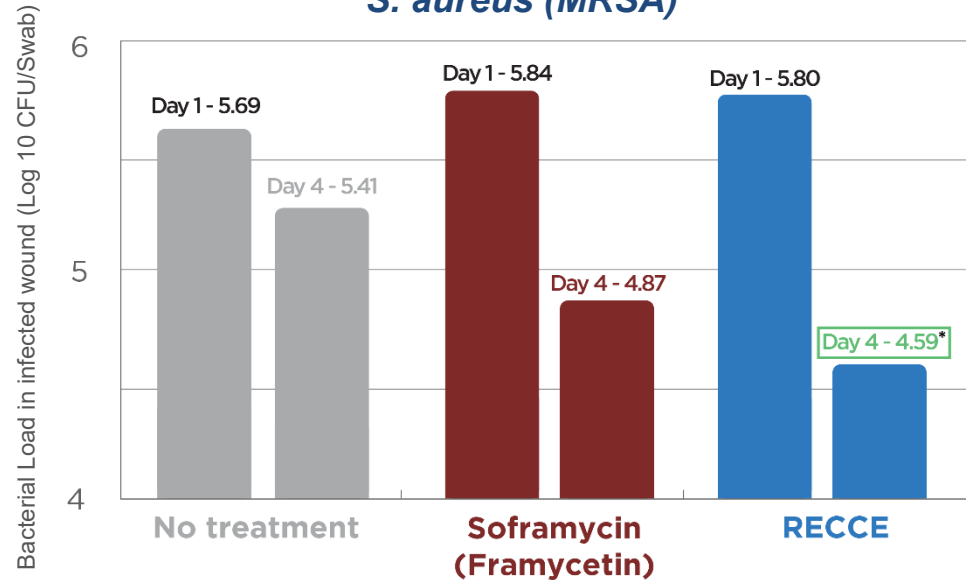
Topical Efficacy – Rat Bacterial Wound Infection

- ▶ **Group 1** – Burn wound with infection, no treatment – sterile topical saline, once daily.
- ▶ **Group 2** – Burn wound with infection + Market drug – Soframycin, twice daily.
- ▶ **Group 3** – Burn wound with infection + RECCE® 327 – topical once daily.

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, whereas there was no significant reduction in bacterial load in the vehicle control ($p>0.05$).”

“**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 when compared to day one although the mean load was lower.”

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



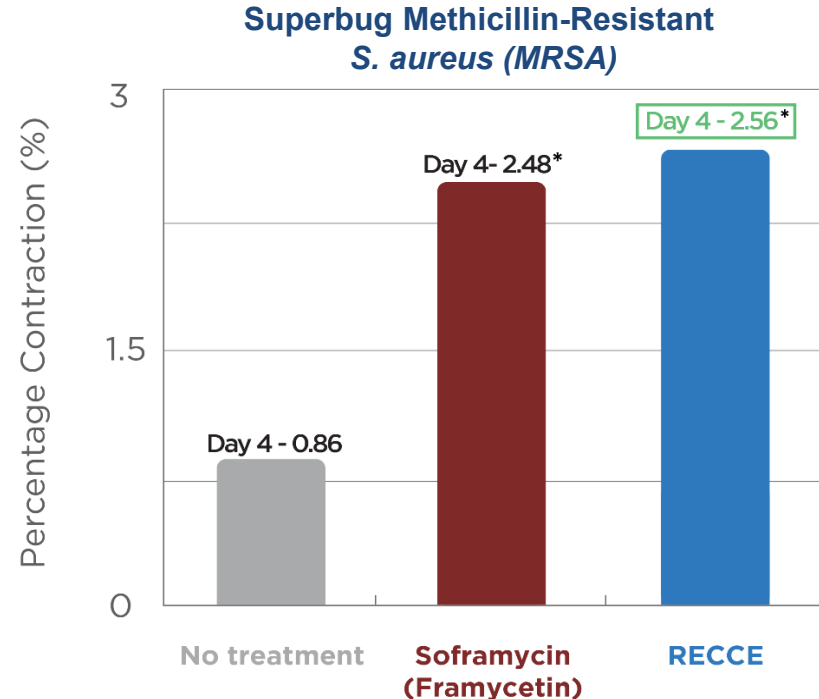
Note: Soframycin is a Marketed topical antibiotic for the treatment of bacterial infections in burns and wounds. It was chosen for its known activity against MRSA.

* Significantly lower than Day 1
Results from an independent laboratory in USA

Topical Efficacy – Rat Wound Contraction (healing)

- ▶ **Group 1** – Burn wound with infection, no treatment – sterile topical saline, once daily.
- ▶ **Group 2** – Burn wound with infection + Market drug – Soframycin, twice daily.
- ▶ **Group 3** – Burn wound with infection + RECCE® 327 – topical once daily.

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.”

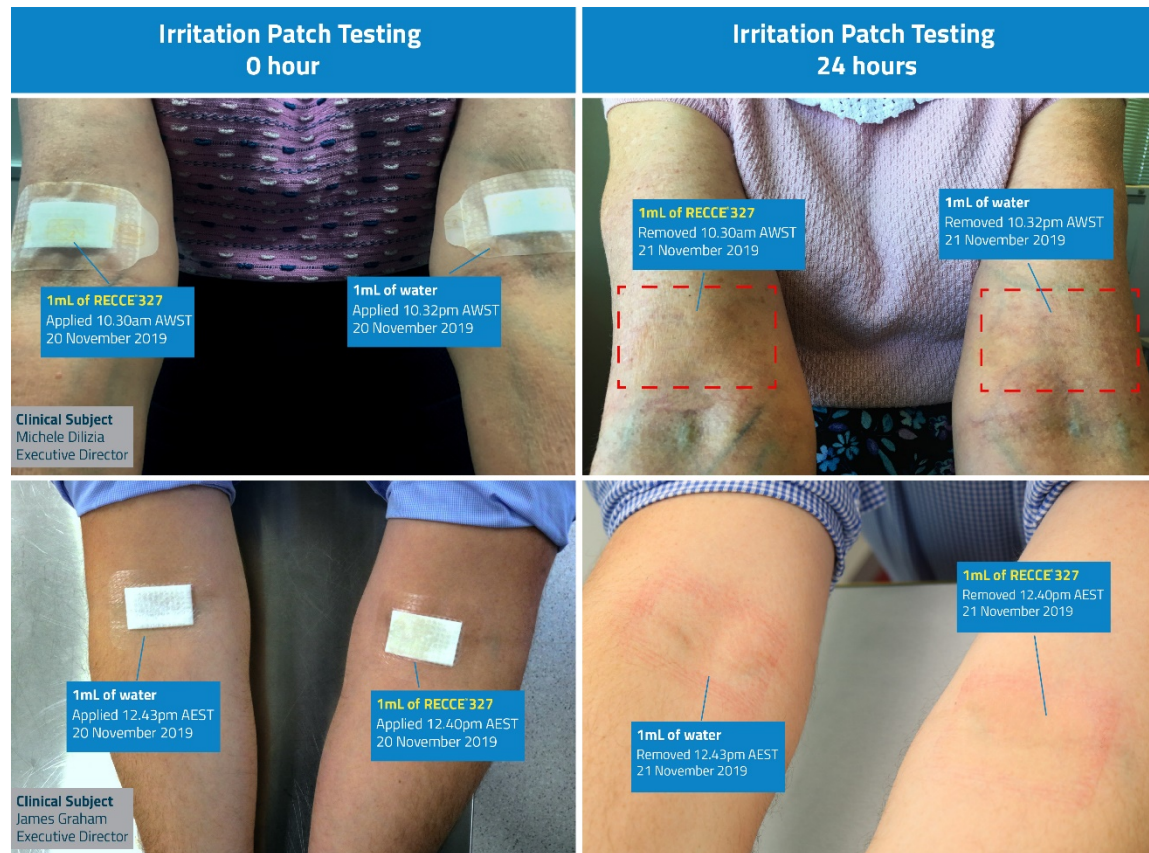


Note: Soframycin is a topically marketed antibiotic for the treatment of bacterial infections in burns and wounds. It was chosen for its known activity against MRSA.

*Significantly different from vehicle control ($p < 0.05$, 1-way ANOVA Results from an independent laboratory in USA)

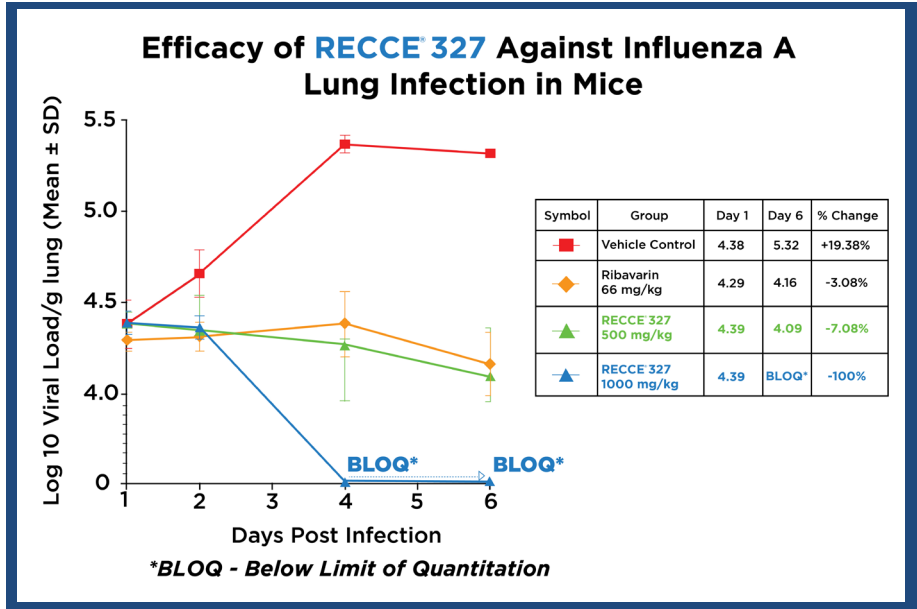
Human Clinical Skin Irritation Test

- ▶ 24-hour human clinical skin irritation test on healthy male and female subject.
- ▶ Recognized irritation study protocol was followed
 - ▶ Supported by qualified internal technicians
- ▶ High concentration, undiluted RECCE® 327 applied on one arm and water on the other arm as negative control
- ▶ After 24-hours, there was **no evidence of discomfort or irritation**, beyond that of the topical adhesive (normal)



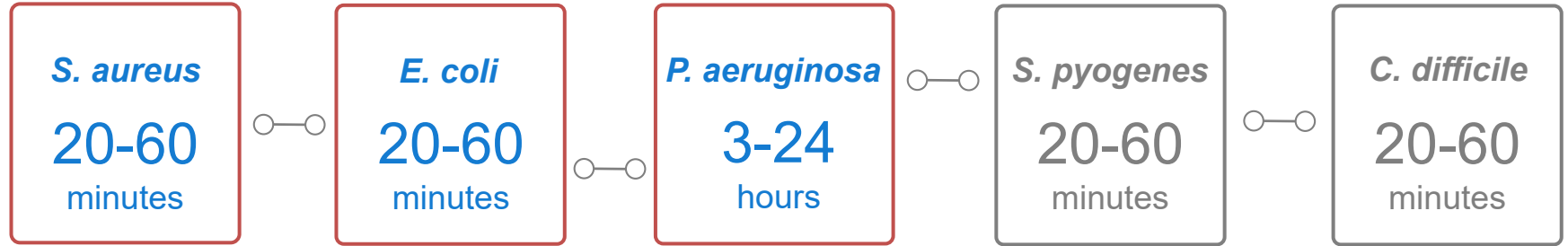
RECCE[®] 327 Efficacy Against Influenza A

- ▶ Study conducted to assess dose-dependent efficacy of RECCE[®] 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[®] 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[®] 327 in other major viral infections**

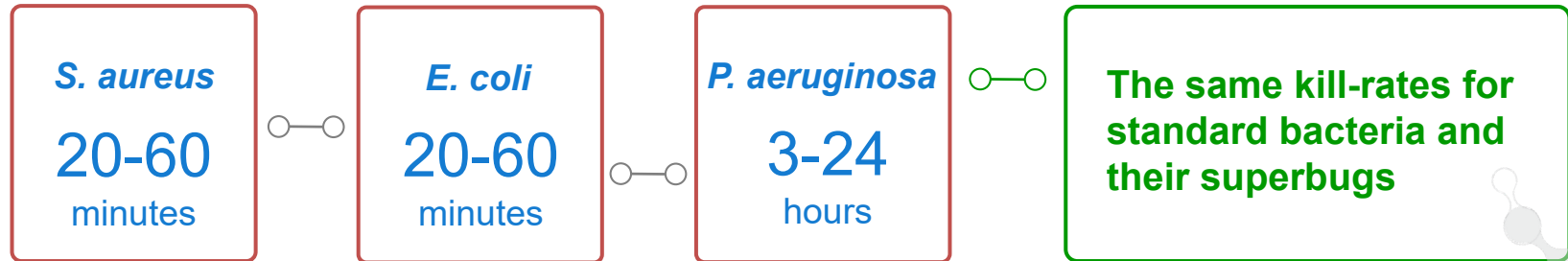


RECCE[®] antibiotics kill at practical speeds

Rates of kill of standard bacteria






Rates of kill of Superbugs



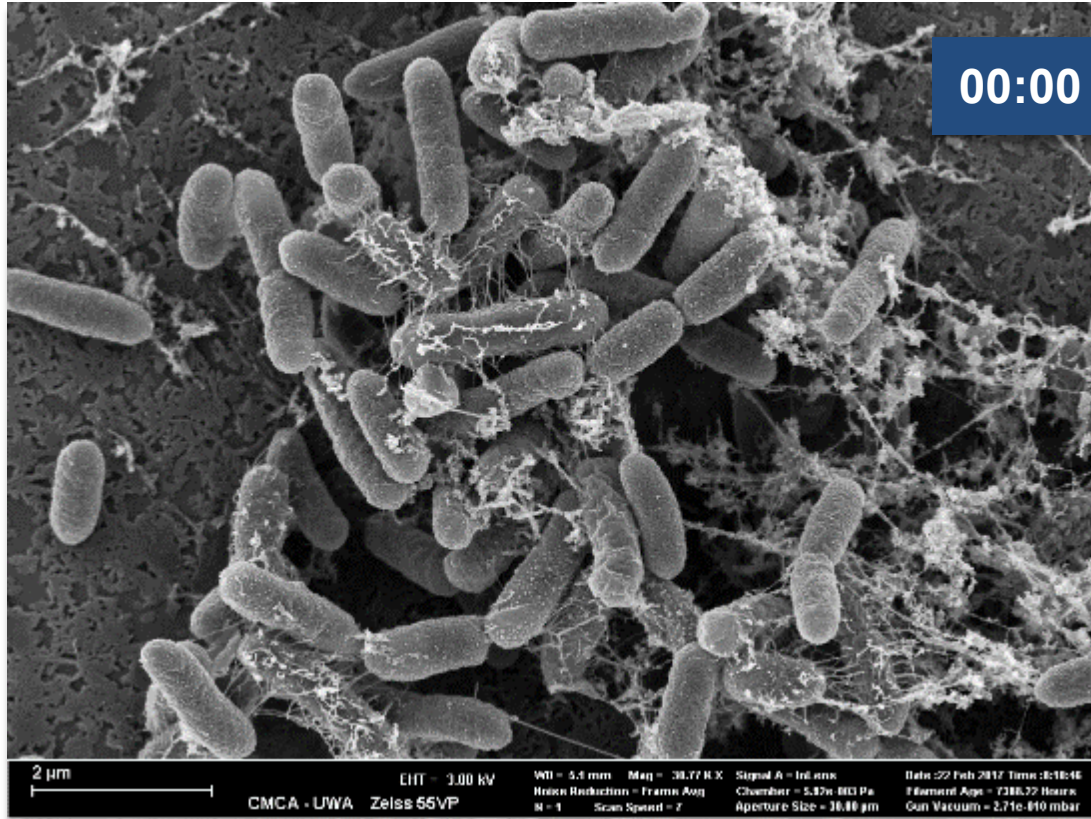
RECCE[®] antibiotics do not Fail¹

Number of repetitive uses before displaying loss of antibiotic activity

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

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

RECCE® 327 Mechanism of Action in practice



00:00 minutes

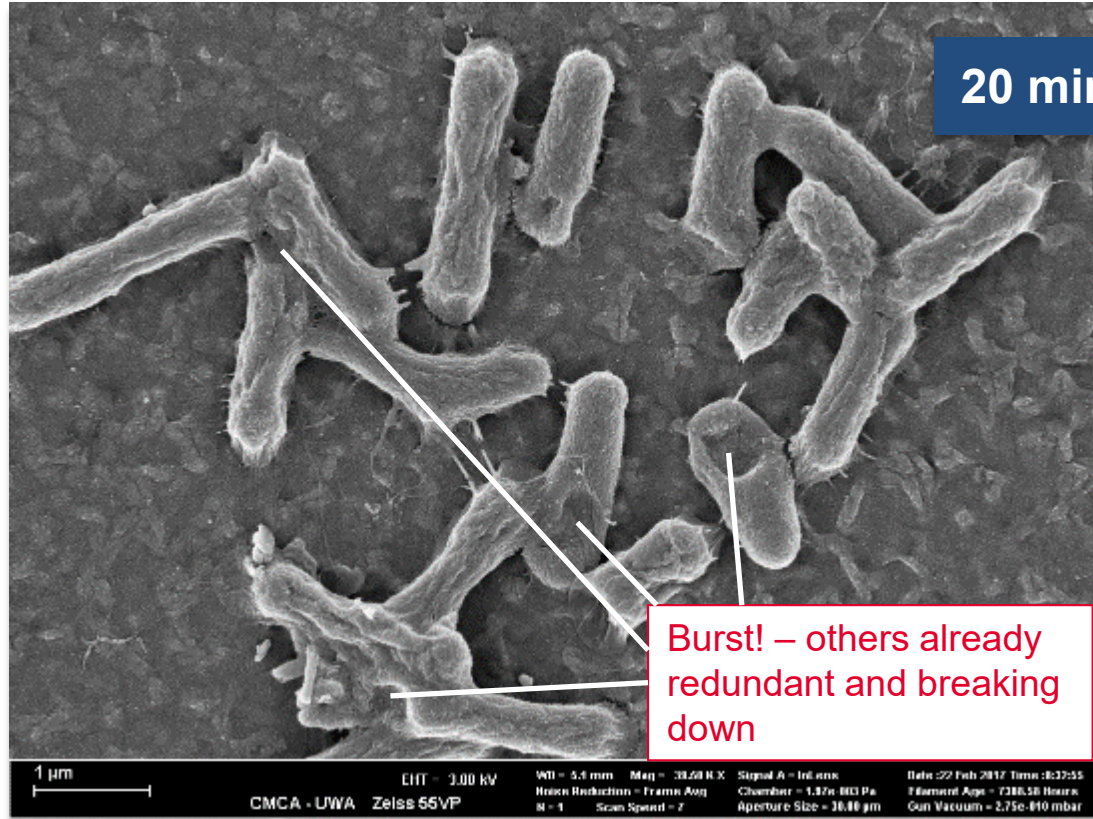
Before application of RECCE® 327, the *E.coli* bacteria cells are healthy, smooth and intact

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

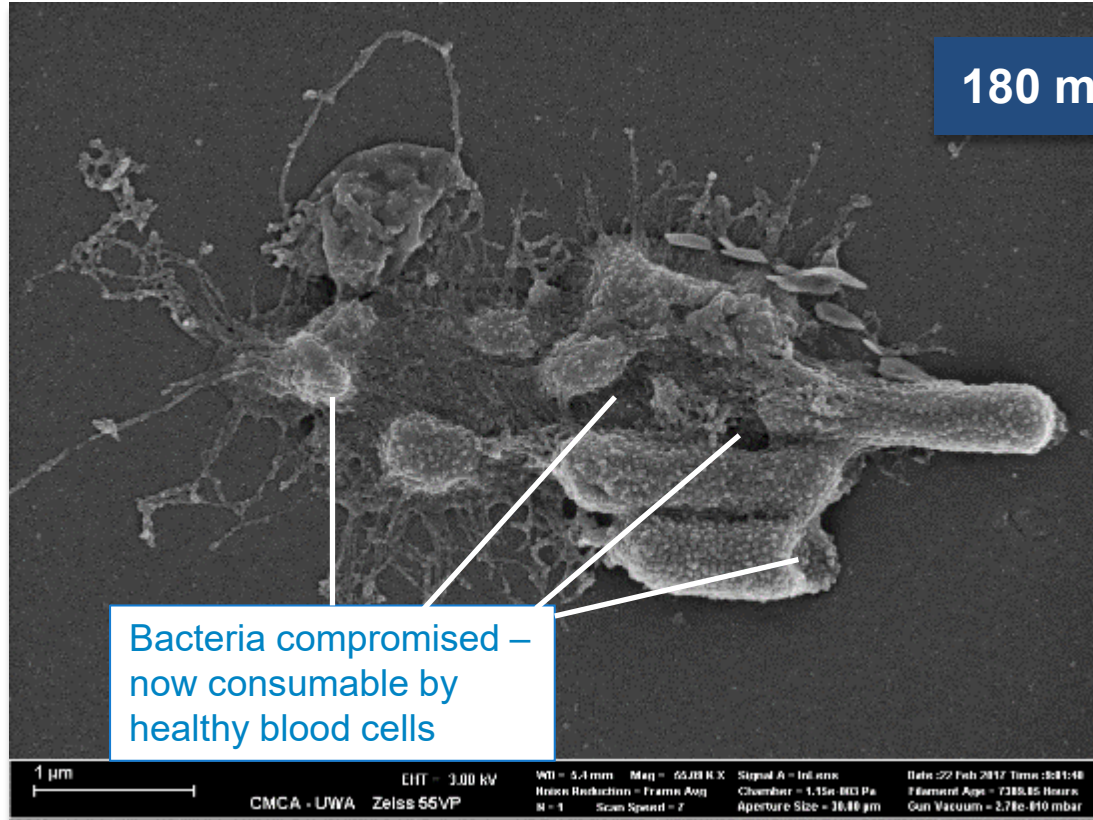


20 minutes

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

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

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**



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



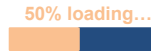
10 years market exclusivity, starting from the date of New Drug Application approval



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



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



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

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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