



***Corporate
Presentation***
ASX:RCE

June 2020

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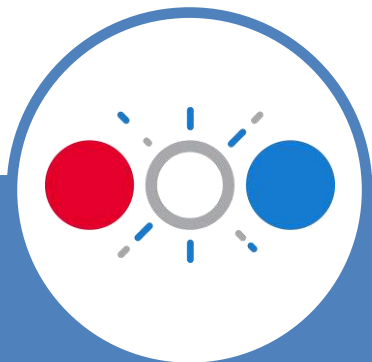
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About Recce Pharmaceuticals Ltd

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).



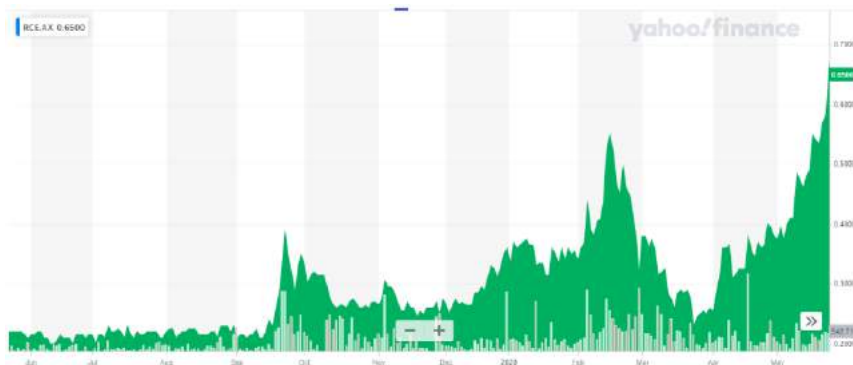
Patented manufacturing, producing to Phase I & II volumes.

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	136.07 million
Share price 25 May 2020	AUD 65 cents
Market Cap (approx.) 25 May 2020	AUD \$88 million
Cash and deposits 31 March 2020	AUD \$4.09 million
Trading range 52 week	AUD 20-65 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!

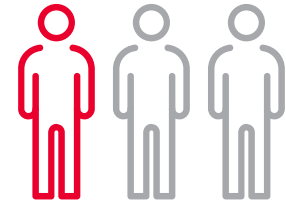
48.9 million incident
cases of **sepsis**
recorded worldwide¹



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

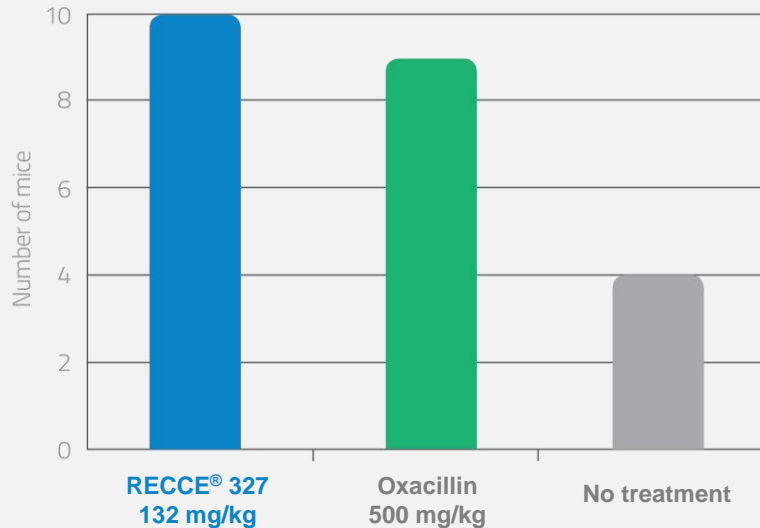
- ▶ Human safety and tolerability study to assess I.V infusion of RECCE[®] 327 in 40 healthy subjects as a single ascending dose
- ▶ Phase I trial agreement with leading clinical research organization PAREXEL
- ▶ First patients expected to be dosed in second half of 2020
- ▶ Estimated clinical start-to-completion 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

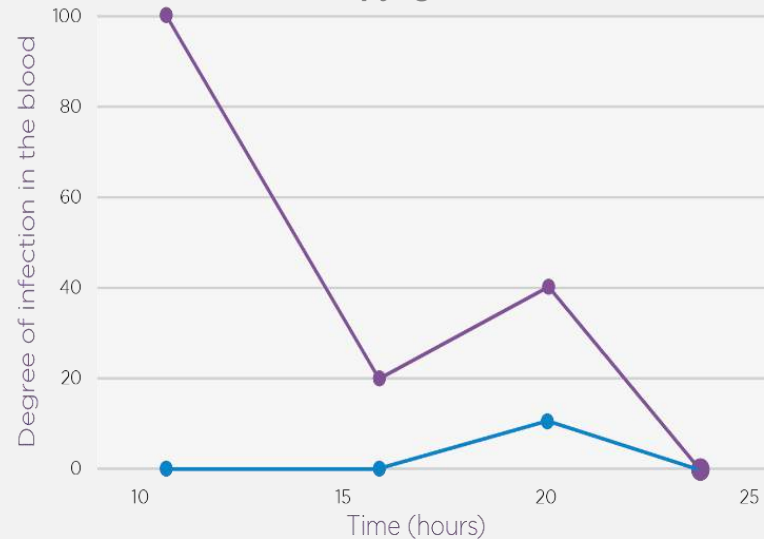
RECCE® Antibiotics – Curative & Preventative IV Studies*

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

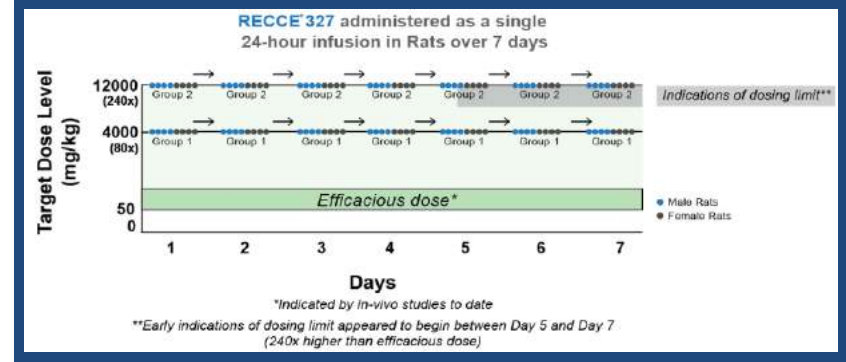
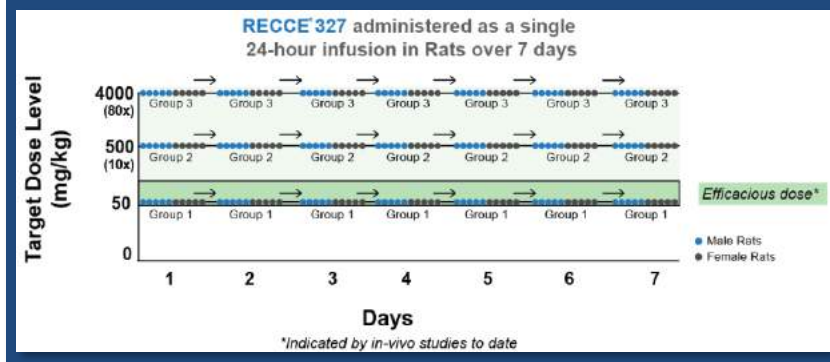
Infection in mice from
S. pyogenes



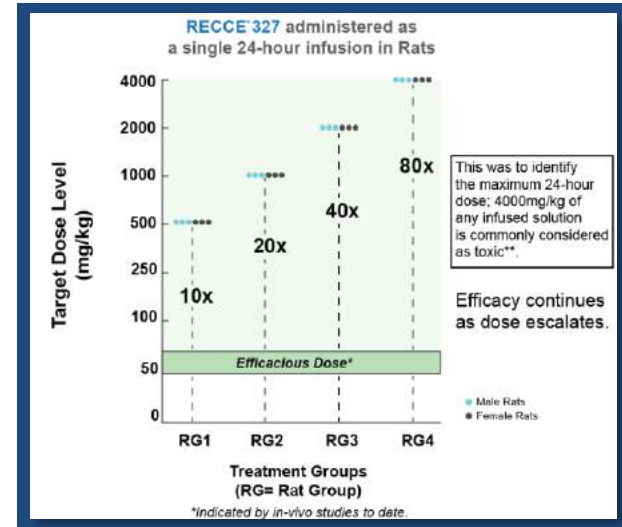
- ▶ **One group of ten mice** were administered a 167 mg/kg dose of RECCE® 327 at 0 hours. **Second group** received no antibiotic.
- ▶ Both groups inoculated with the *S. pyogenes* burden into the bloodstream.
- ▶ Mice results first monitored after 12 hours allowing bacteria to develop and establish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

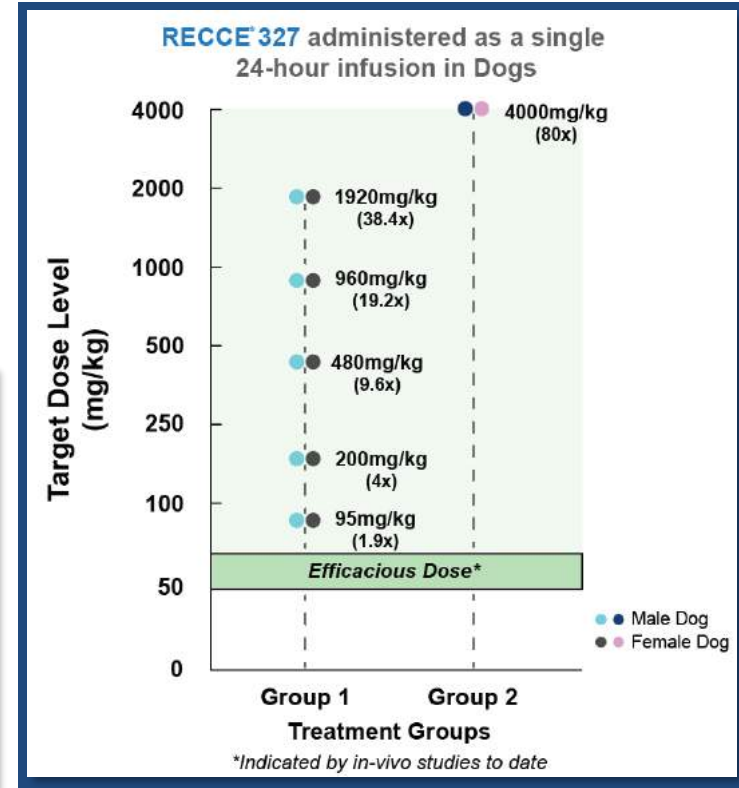
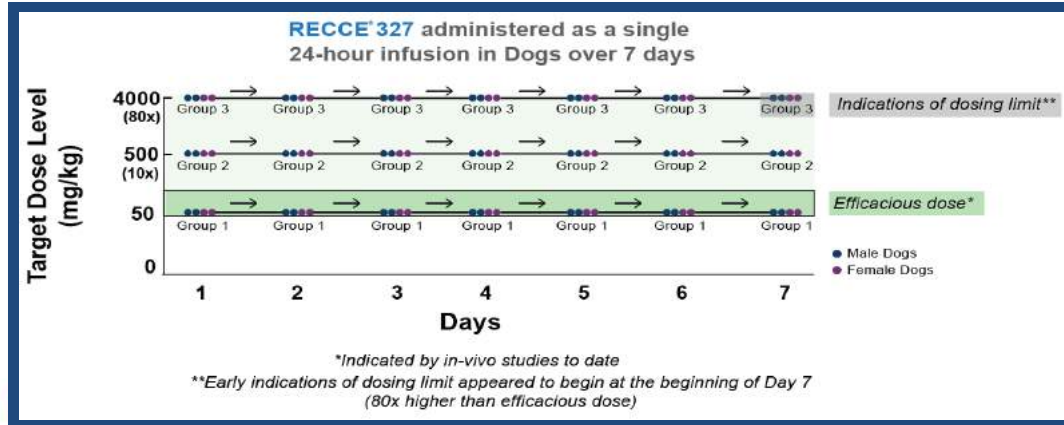


- ▶ **No Observed Adverse Effect Level (NOAEL) of 24-hour 500mg/kg (10x indicated efficacious dose)**
- ▶ Phase Ia (24-hour), Phase Ib (24-hour over 7 days)
 - ▶ A separate single 24-hour intravenous infusion administration of RECCE® 327 up to 12,000 mg/kg over the course of 7-days was carried out.
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

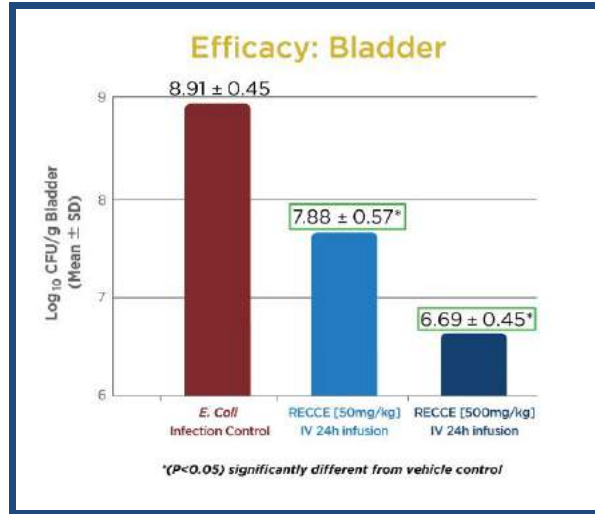


Single Dose and Range-Finding Repeat Dosing - Dogs

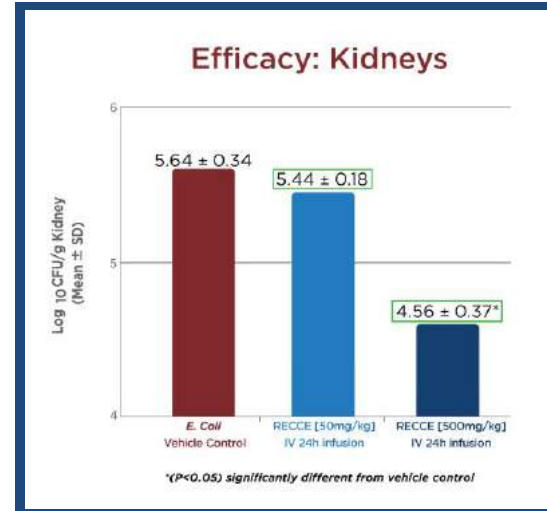
- ▶ **No Observed Adverse Effect Level (NOAEL) of 24-hour 500mg/kg (10x indicated efficacious dose)**
- ▶ Phase Ia (24-hour), Phase Ib (24-hour over 7 days)
- ▶ A single 24-hour intravenous infusion administration of RECCE® 327 up to 4000 mg/kg and 7-day continuous intravenous infusion administration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

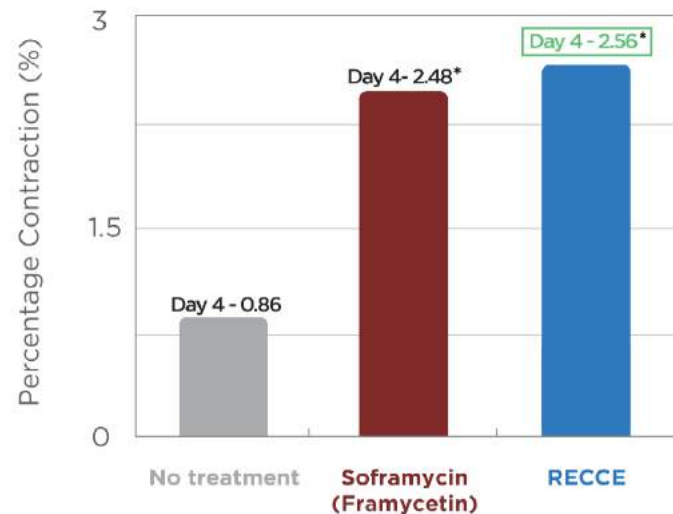
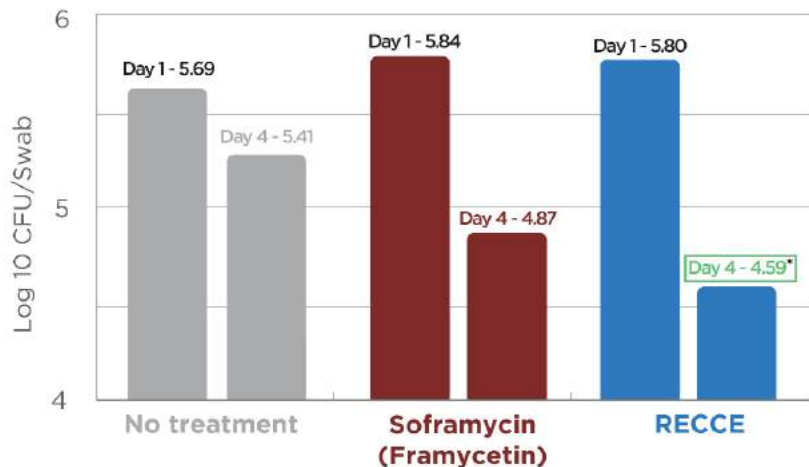


- Group 1** – Kidney *E. Coli* infection + vehicle control
- Group 2** – Kidney *E. Coli* infection + RECCE® 327 50mg/kg
- Group 3** – Kidney *E. Coli* infection + RECCE® 327 500mg/kg

- ▶ 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

Topical Efficacy –Wound Infection & Contraction

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

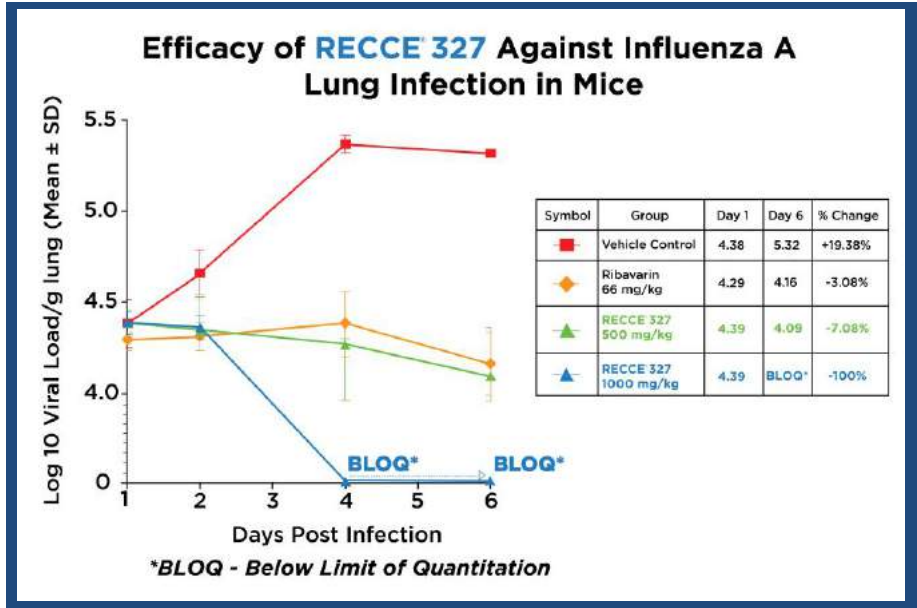


The Study Director noted: “**RECCE® 327** (100 µl (19.15 mg/ml), topical, once daily, over three days), and **Soframycin** (30 mg, topical, twice daily, Q=12hr, over three days) **showed a significant reduction wound on day four** ($p<0.05$) when compared to day one, when compared to the vehicle control.”

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...**”

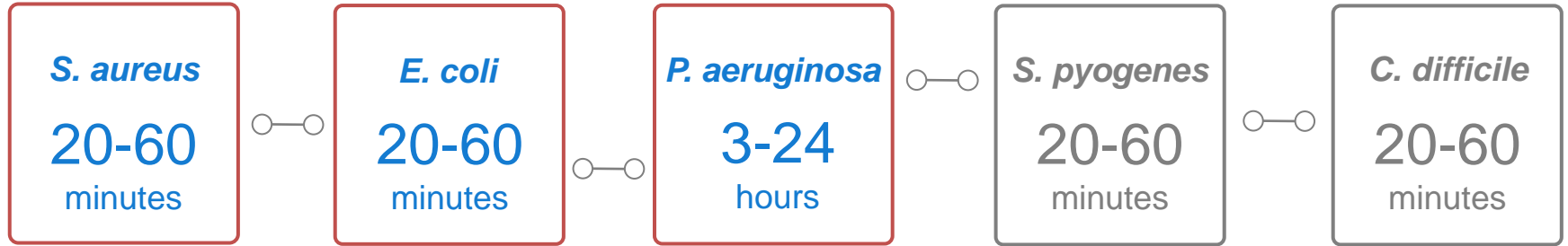
RECCE[®] 327 Efficacy Against Influenza A

- ▶ 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**

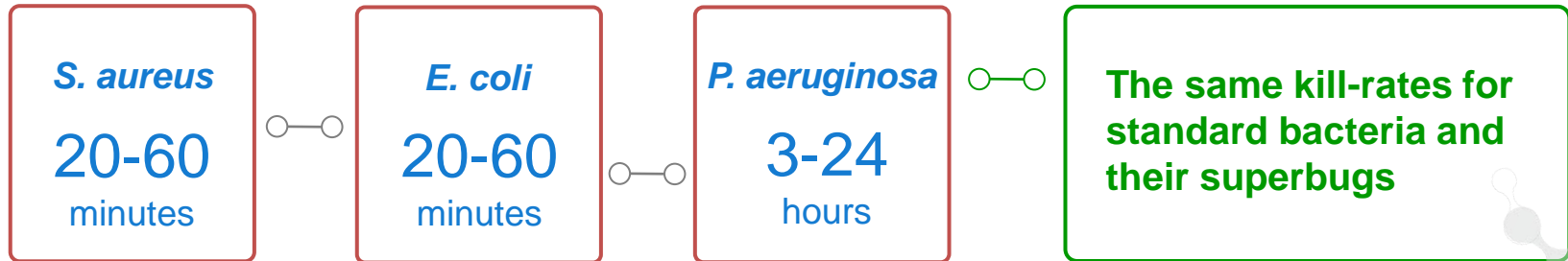


RECCE[®] antibiotics kill at practical speeds

Rates of kill of standard bacteria






Rates of kill of Superbugs



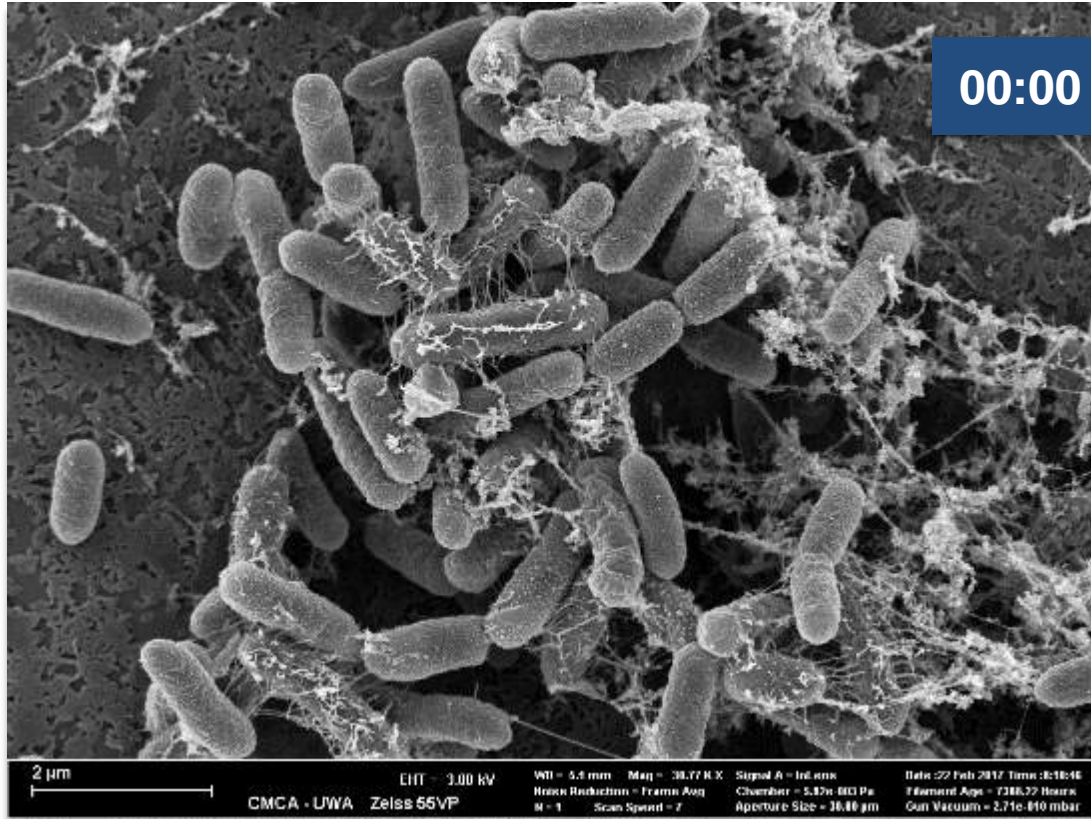
RECCE® antibiotics do not Fail¹

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

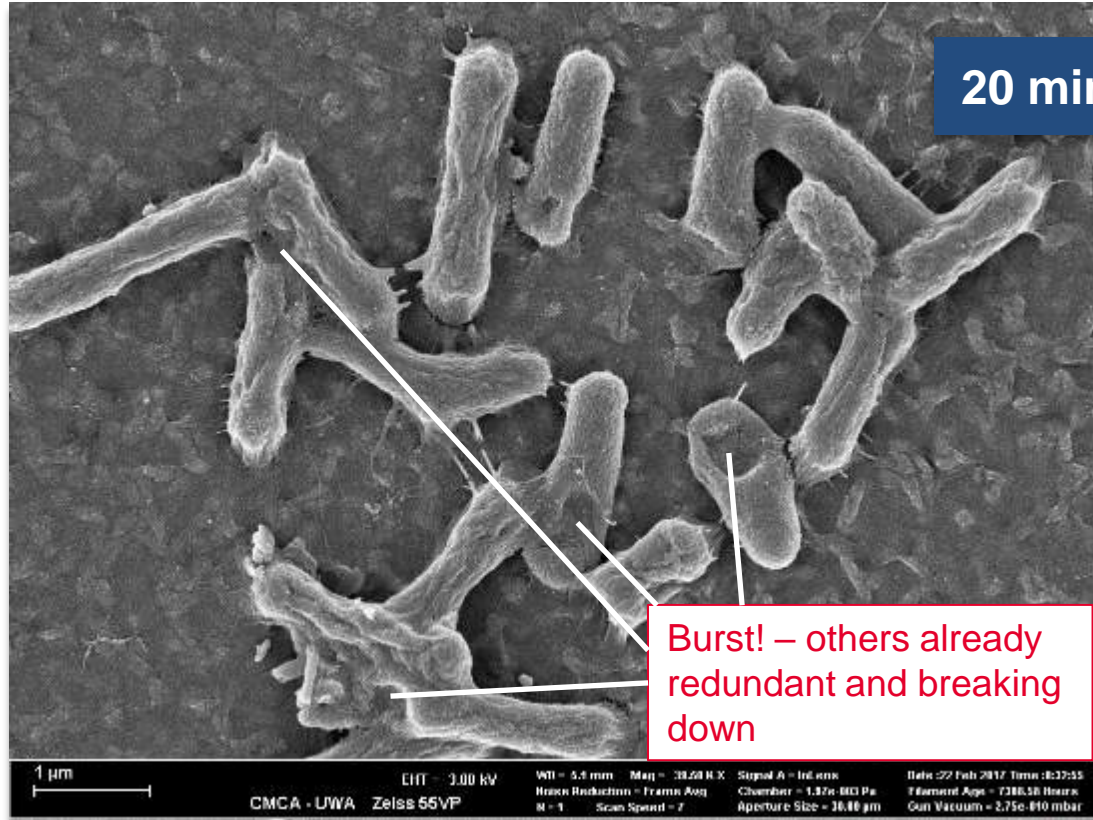
Before application of RECCE[®] 327, the *E.coli* bacteria cells are healthy, smooth and intact

E.coli Facts¹

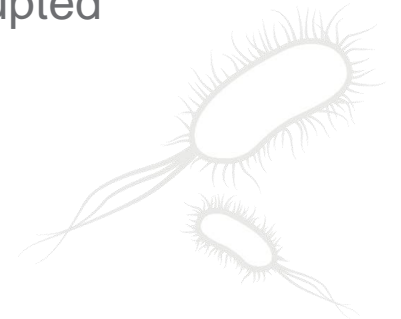
- Part of the Enterobacteriaceae family
- **\$1.2bn USD** estimated attributable healthcare costs in 2017
- CDC labels this bacteria as a **Serious Threat**
- **50% increase** in cases since 2012

¹CDC Antibiotic Resistance Report 2019

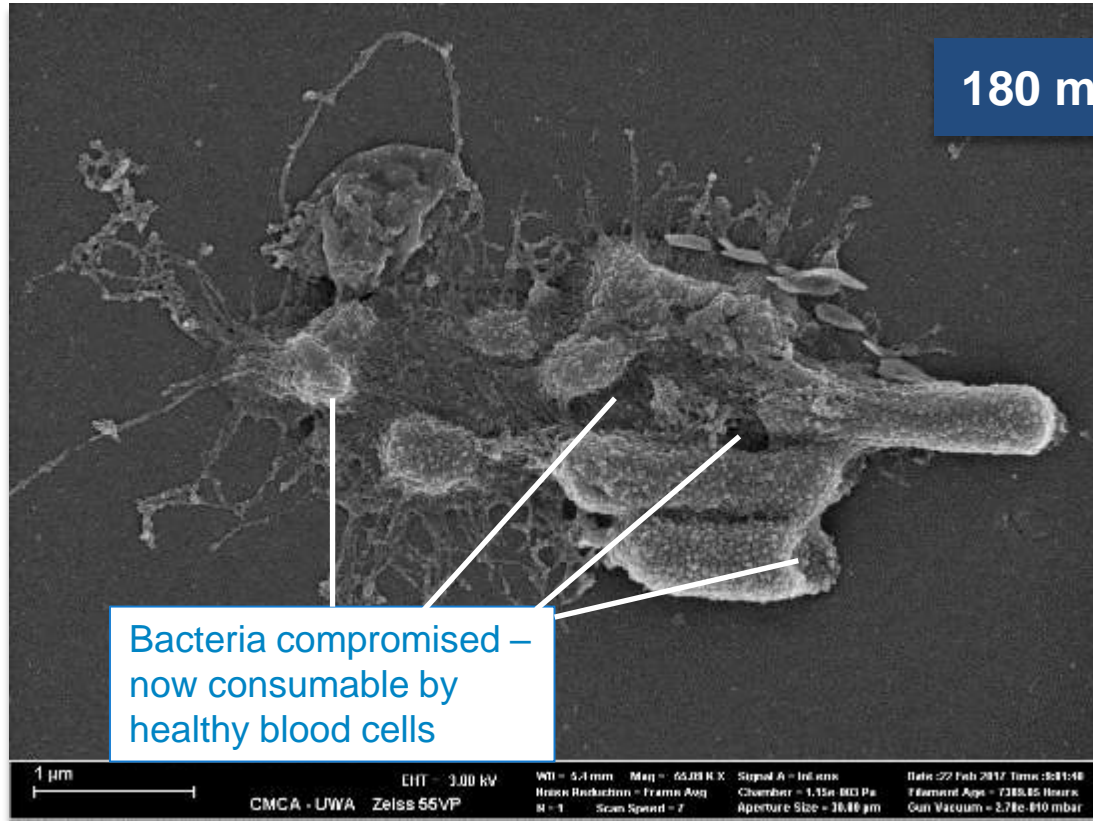
RECCE® 327 Mechanism of Action in practice



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 <u>Granted</u>	Expiry	Patent Family 2/3	Expiry	Trademarks registered
Australia	✓	2028	✓	2035	✓
USA	✓	2029	✓	2035	✓
Europe	✓	2028	✓	2035	✓
Germany	✓	2028	✓	2035	-
Spain	✓	2028	✓	2035	-
France	✓	2029	✓	2035	-
United Kingdom	✓	2028	✓	2035	-
Italy	✓	2028	✓	2035	-
Sweden	✓	2028	✓	2035	-
Japan	✓	2028	✓	2035	✓
China	✓	2028	Pending	2035	✓

Patent Family 1 – granted

Unique and highly economical manufacturing process

Patent Family 2 – pending

Applications (Multi-drug delivery)

Patent Family 3 – pending

Anti-viral uses

Trademarks

RECCE® for use on pharmaceutical products and services

Manufacturing and Production



Wholly owned, automated manufacturing facility in Sydney's Macquarie Park



- ▶ Raw materials plentiful and **CHEAP** – few \$/KG
- ▶ **No expensive waste** – 99.9% product yield.



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



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



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

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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