ASX Announcement

Recce Pharmaceuticals
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Recce Pharmaceuticals Opening R&D Address at World Anti-Microbial Resistance Congress 2021

Sydney Australia, 8 November 2021: Recce Pharmaceuticals Ltd (**ASX:RCE, FSE:R9Q**) (**Company**), the Company developing New Classes of Synthetic Anti-infectives, today announced it will be delivering the Opening R&D Address at the World Anti-Microbial Resistance (AMR) Congress 8th-9th November 2021.

Recce Chairman, Dr John Prendergast will deliver the 20-minute Opening R&D Address, highlighting the urgent need for new antibiotics to address the rapidly growing threat of AMR. Dr Prendergast's presentation ***"Synthetic Anti-Infectives: Embracing New Technology",*** highlighting Recce's unique Mechanisms of Action, infectious disease pipeline of new drug candidates – positioning Recce as a sign of new hope in the global fight against superbugs on the international stage.

The two-day World AMR Congress held in Washington DC is the largest AMR conference in the world with more than 1,000 attendees from over 50 countries. The congress attracts industry leaders, clinicians, healthcare payers, and medical regulators from around the world.

Claire Murphy, Production Director, World Anti-Microbial Congress says: "Antimicrobial resistance is an urgent public health crisis that needs global attention, now more than ever. The World AMR Congress continues to be the go-to platform for leading antibiotic developers, such as Recce Pharmaceuticals, to connect with global AMR stakeholders and further initiatives aimed at combatting antimicrobial resistance."

WORLD ANTI-MICROBIAL RESISTANCE CONGRESS 2021

The presentation is provided below and will also be made available on the Company's website in due course.

This announcement has been approved for release by Recce Pharmaceuticals Board.

Recce Pharmaceuticals

ASX:RCE FSE:R9Q

SYNTHETIC ANTI-INFECTIVES: EMBRACING NEW TECHNOLOGY

WORLD ANTI-MICROBIAL RESISTANCE CONGRESS | 2021

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A Global Threat – Antibiotic Resistance

"To State the Obvious"

- Occurs when bacteria change to protect themselves from an antibiotic and cause these medicines to lose their effectiveness.
- One of the biggest threats to global health and food security today.
- Leads to longer hospital stays, higher medical costs and increased mortality.
- A growing number of infections are becoming harder to treat as the antibiotics used to treat them become less effective.
- Occurs naturally, but misuse in humans & animals is accelerating the process.
- Affects anyone, of any age, in any country.

https://www.who.int/news-room/fact-sheets/detail/antibiotic-resistance

Antimicrobial Agents Divided into Groups based on the Mechanism of Antimicrobial Activity

Agents that inhibit cell wall synthesis

Depolarize the cell membrane

Inhibit protein synthesis

Inhibit nuclei acid synthesis

Inhibit metabolic pathways in bacteria

Table 1.

Antimicrobial groups based on mechanism of action.

Mechanism of Action	Antimicrobial Groups
Inhibit Cell Wall Synthesis	β-Lactams
	Carbapenems
	Cephalosporins
	Monobactams
	Penicillins
	Glycopeptides
Depolarize Cell Membrane	Lipopeptides
Inhibit Protein Synthesis	Bind to 30S Ribosomal Subunit
	Aminoglycosides
	Tetracyclines
	Bind to 50S Ribosomal Subunit
	Chloramphenicol
	Lincosamides
	Macrolides
	Oxazolidinones
	Streptogramins
Inhibit Nucleic Acid Synthesis	Quinolones
	Fluoroquinolones
Inhibit Metabolic Pathways	Sulfonamides
	Trimethoprim

Table 1: Examples of drugs from each of these groups

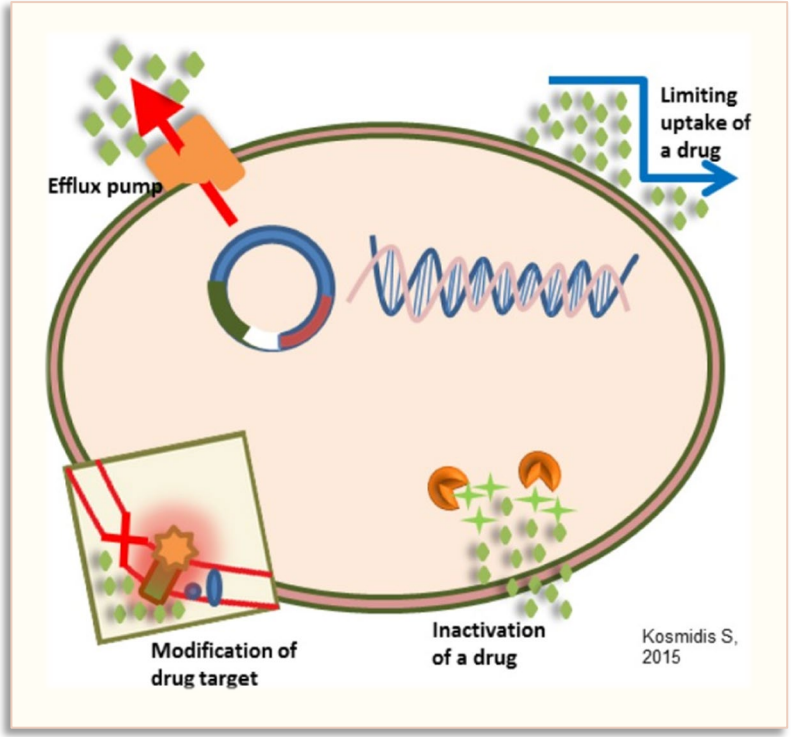
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6604941/

Antibiotic Resistance Mechanisms

Four main categories:

- **Limiting uptake of a drug**
- **Inactivating a drug**
- **Modifying a drug target**
- **Active drug efflux**

- **Intrinsic resistance** may make use of limiting uptake, drug inactivation, and drug efflux;
- **Acquired resistance** may make use of drug target modification, drug inactivation, and drug efflux;
- **Gram-negative bacteria** make use of all four main mechanisms;
- **Gram-positive bacteria** less commonly use limiting the uptake of a drug since they don't have an LPS outer membrane nor the capacity for certain types of drug efflux mechanisms.



https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6604941/

Contributors to Antibiotic Resistance

The emergence and spread of drug-resistant pathogens that have acquired new resistance mechanisms continues to threaten our ability to treat common infections.

- **Increased consumption of antimicrobial drugs**
  - Both by humans and animals; and, improper prescribing of antimicrobial therapy.
- **Overuse of many common antimicrobials agents by physicians may occur**
  - The choice of drug is based on a combination of low cost and low toxicity.
- **Improper prescribing of antimicrobials drugs**
  - Initial prescription of a broad-spectrum drug that is unnecessary, or ultimately found to be ineffective for the organism(s) causing the infection.
- **Prior use of antimicrobial drugs**
  - Puts a patient at risk for infection with a drug resistant organism, and those patients with the highest exposure to antimicrobials are most often those who are infected with resistant bacteria.

***Most antimicrobial compounds are naturally-produced molecules**, and, as such, co-resident bacteria have evolved mechanisms to overcome their action in order to survive.*

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6604941/

A Common Failure Associated with Existing Antibiotics

*With such a **wide range of mechanisms**, on face value, there **should be better control** over the organisms.*

*However, **inability to address this problem** has forced **improper stewardship** of antimicrobial agents **leading to this tremendous resistance** issue.*

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4888801/

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 MoA - 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!

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1- Lee, C E et al. "The incidence of antimicrobial allergies in hospitalized patients: implications regarding prescribing patterns and emerging bacterial resistance." Archives of internal medicine vol. 160,18 (2000): 2819-22. doi:10.1001/archinte.160.18.2819

The Pew Charitable Trusts Antibiotic Treatment List*

- RECCE® 327 (R327) included in The Pew Charitable Trusts' annual list of ***"Non-traditional Products in Development to Combat Bacterial Infections Register".***
- New "outside-the-box" drugs are critically needed, with conventional antibiotic pipeline extremely thin.
- As of 3/31, 36 non-traditional candidates are in clinical development ranging from vaccines to immunotherapies.
- **R327 is the only synthetic polymer drug candidate for treating sepsis currently in development.**

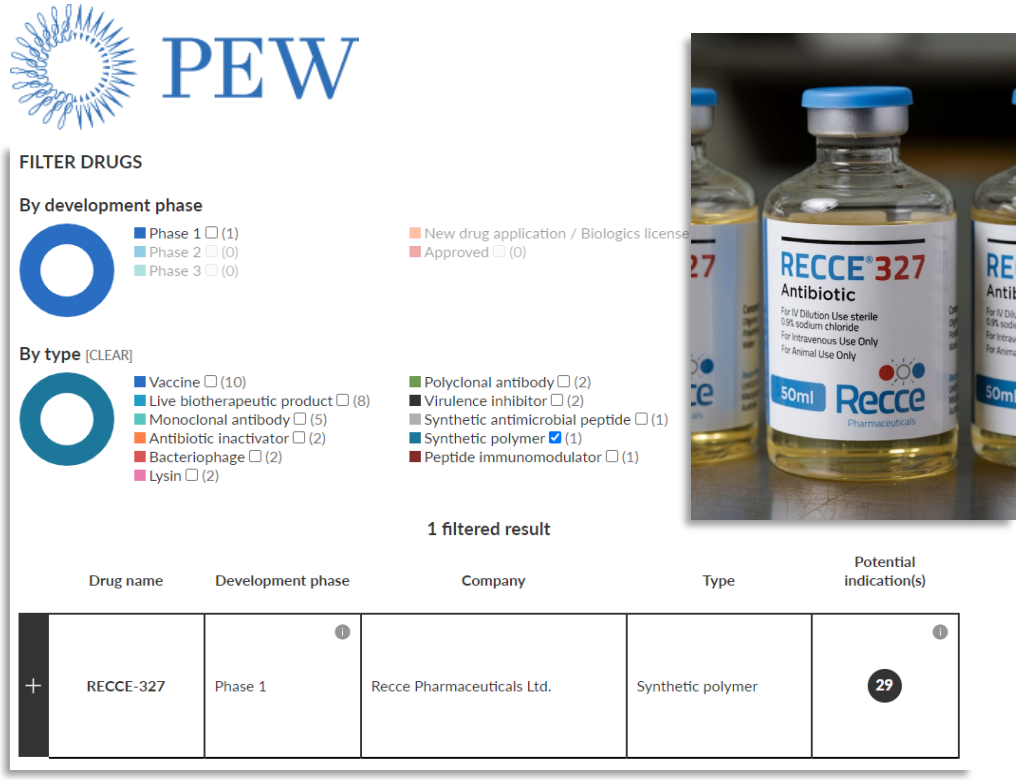


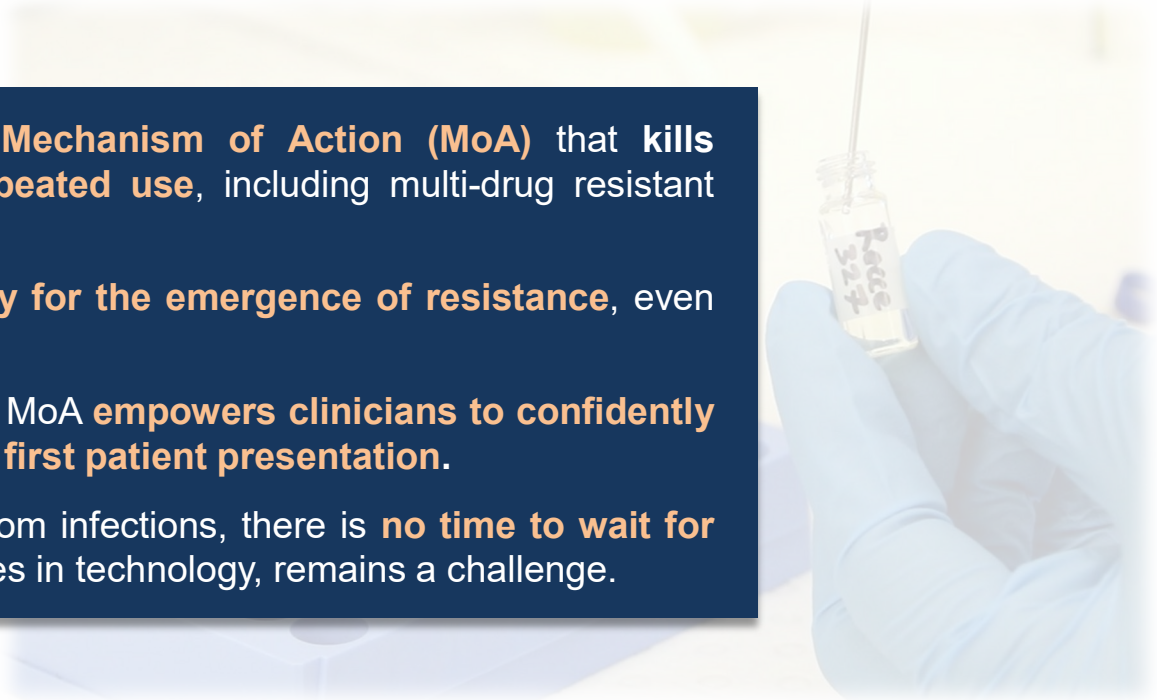
Image Source: The Pew Charitable Trusts 2021

*https://www.pewtrusts.org/en/research-and-analysis/data-visualizations/2017/nontraditional-products-for-bacterial-infections-in-clinical-development

Recce's Anti-infective Platform:

Addressing the Historic Lack of Innovation

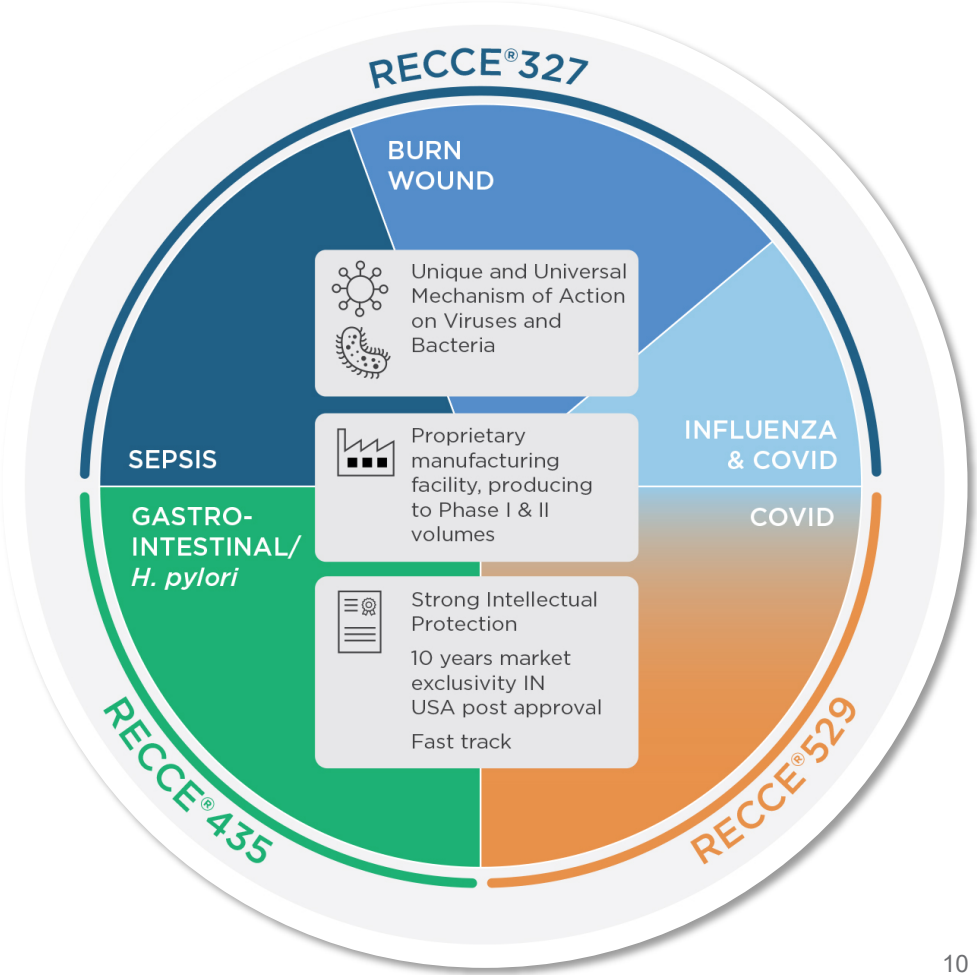
- R327 has a **universal, multi-layered Mechanism of Action (MoA)** that **kills bacteria** and **keeps on killing with repeated use**, including multi-drug resistant superbug forms.
- Recce's anti-infectives show **no tendency for the emergence of resistance**, even after repeated use.
- Broad-spectrum capability and fast-acting MoA **empowers clinicians to confidently and quickly administer the antibiotic at first patient presentation.**
- When patients are rapidly deteriorating from infections, there is **no time to wait for clear diagnostics** which, despite advances in technology, remains a challenge.



https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4888801/

A Versatile Technology Platform

- **Anti-infective** focused Biotech company targeting both bacterial and viral indications.
- **Strong IP** and **own manufacturing** capability.
- **Versatile platform** delivering oral, intravenous and spray formulations for a range of use-cases.
- Designed to safely provide treatment **without developing resistance** over time.
- Multiple clinical opportunities with R327 interim **first in human** data expected in 2021.



RECCE® 327 – A Synthetic Polymer

A stable, safe and highly efficacious polymer

Monomers/Polymers

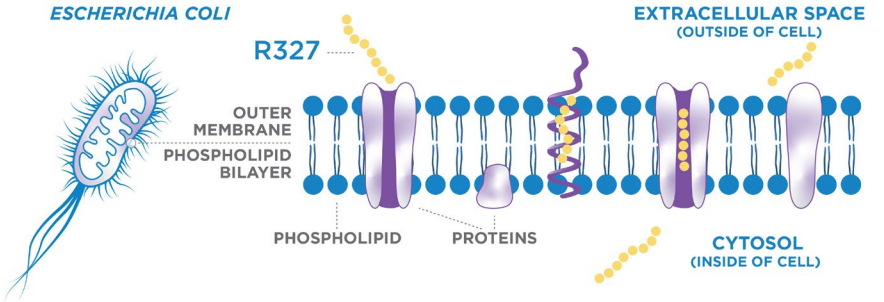
- Synthetic polymers consist of large molecules
  - Composed of many repeating monomers
- Polymers play essential and ubiquitous roles in everyday life
- Acrolein polymers are typically unstable in physiological conditions
- The polymerisation of acrolein first reported in 1843 – producing a solid polymer which was insoluble in all common solvents and of no significant use.

- Raw active ingredient **polymerised** to create R327
- **R327 is a 1-1.5kDa stable polymer**
- **100% Soluble at all pH's** – even to the very acidic (low) pH of the stomach
- Ability to **synthesize polymer-antibiotic** of chosen molecular weight
  - Facilitate activity in areas outside of intestinal tract
- **Accurate manufacturing reproducibility** of R327 across multiple batches

Independent Study Undertaken on R327's MoA[1]

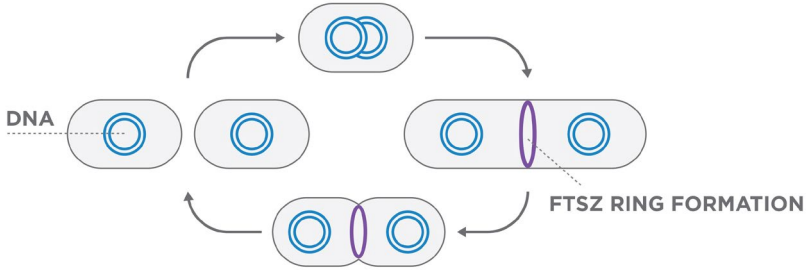
By World Leaders in Bacterial MoA Analysis

Stage 1



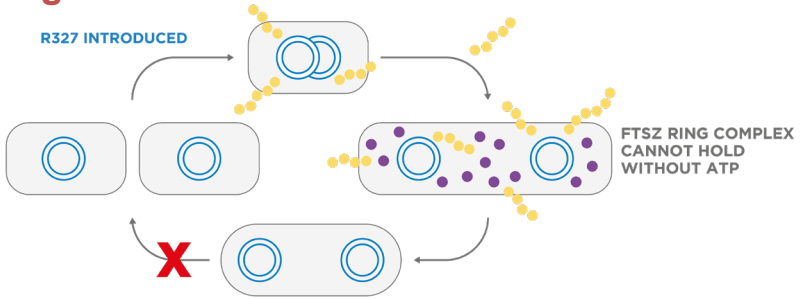
R327 permeabilizes cell membrane & enters the cell

Stage 2



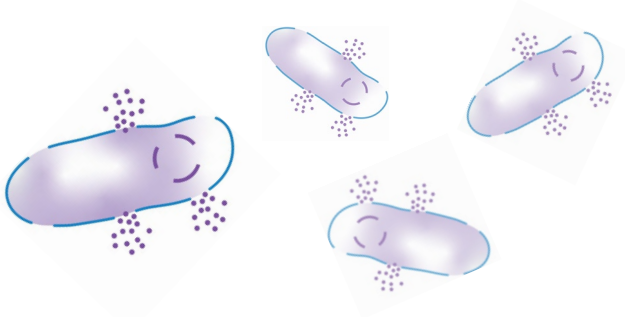
R327 interrupts bacterial cellular energetics via ATP Synthesis

Stage 3



Cellular division & non-dividing cell functions are disrupted

Stage 4



R327 rapidly & irreversibly bactericidal & at high concentrations cell lysis

1 – Tsunemoto, H., Quach, D. et al. Elucidating the Mechanism of Action of Novel Polymer-based Synthetic Anti-infective Compound RECCE 327 - Abstract

RECCE® 327 Multi-Layered Mechanism of Action

R327 rapidly & irreversibly shuts down cellular energetics (adenosine triphosphate (ATP) production) – primary MoA

R327 affects the assembly of bacterial cell division complex, components that require cellular energy to remain assembled, confirming its ability to disrupt cellular bioenergetics

R327 results in the decreased formation of the bacterial cell division complex into ring-like structures (Z-rings) in a concentration dependent manner

R327 permeabilises the cell membrane/alters the integrity of the outer membrane of *E. coli* cells – intended activity without toxicity

At higher concentrations and subsequent to ATP shut down cell lysis can occur as a further MoA (bacterial bursting due to their uniquely high internal pressure)

R327 rapidly and irreversibly bactericidal to slow-growing quiescent or stationary phase *E. coli* cells in addition to actively dividing *E. coli* cells

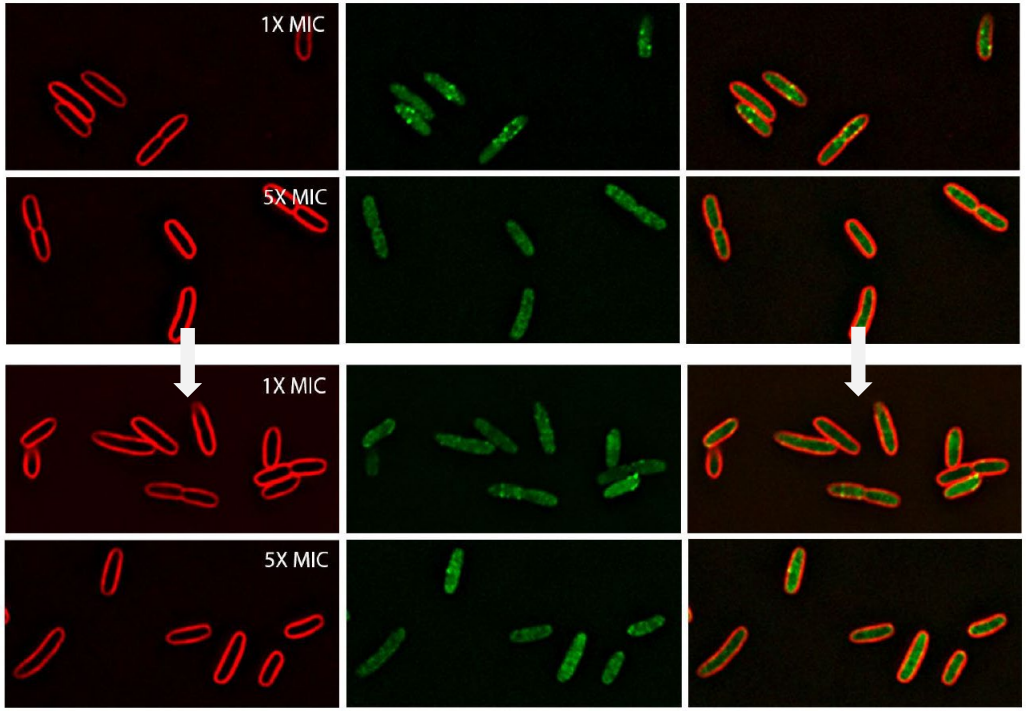
Within a minute, the highest concentration of R327 used, 5x MIC, was **observed to reduce viable cell counts** reported as cell forming units per millilitre of culture (CFU/ml) 100-fold (>$1x10^7$ to $1x10^5$ at timepoint 0)

Current antibiotics rarely retail bactericidal activities against non-dividing or stationary phase bacterial cells; however, R327 showed remarkable activity against slow-growing bacteria, indicating potential antibacterial activity in biofilms

In comparison to ampicillin and ciprofloxacin, **R327 is able to outperform both of these antibiotics** in bactericidal activity (measured by viable cell counts) against stationary cells

RECCE® 327 Mechanism of Action in Practice

Treatment of R327 against E. coli at 1x and 5x MIC leading to disassembly of the FtsZ-GFP rings, supporting initial studies which indicated R327 inactivates cellular bioenergetics and is rapidly and irreversibly bactericidal.



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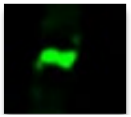
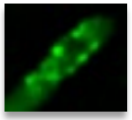


***FtsZ rings** – a protein essential for cell division (bacteria reproduction)*



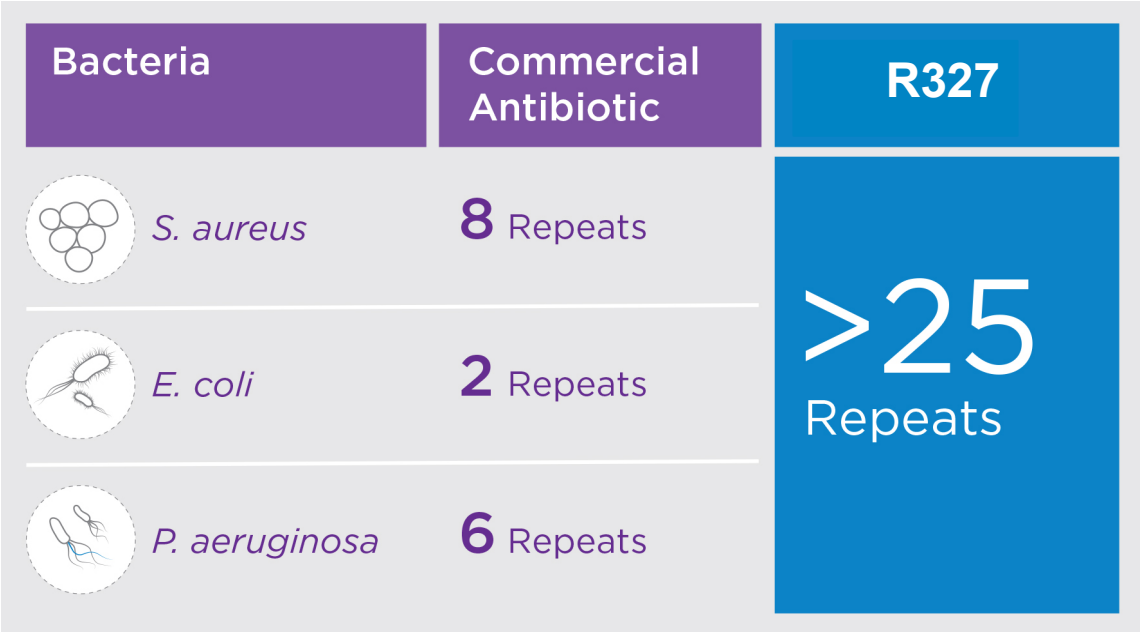
***Dissassembled FtsZ rings** - indicating the loss of ability for bacteria to reproduce*

E. coli, expressing FtsZ-GFP, treated with R327, PEG200 and Control Antibiotics after **60 minutes of treatment**

Mechanism of Action Studies; Source: Linnaeus Biosciences Inc. San Diego.

RECCE® 327 Does Not Lose Activity![1]

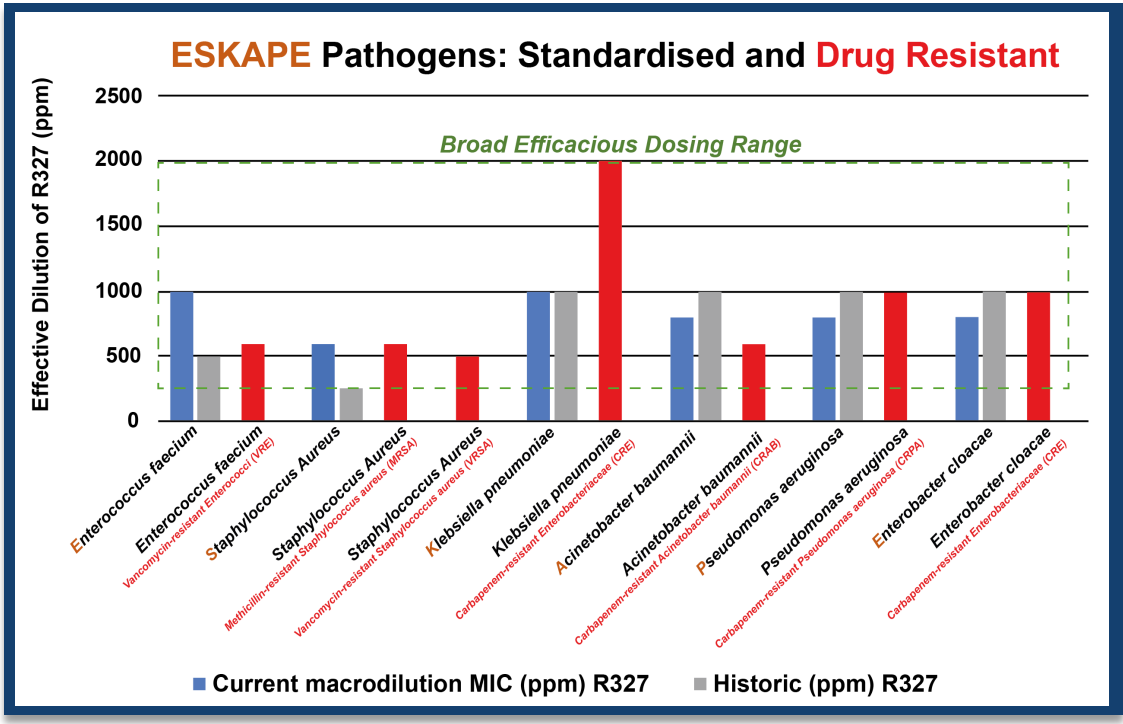
Number of repetitive uses before displaying loss of antibiotic activity



[1] After repetitive use, the commercial antibiotic loses activity; >25 repeats **R327 DOES NOT**

ESKAPE Pathogens Can't Escape R327

- Bactericidal activity of R327 demonstrated a **three-log** or **99.9% reduction** against all **ESKAPE** strains over 24 hrs at various concentrations and times
- **R327 remains effective against hypermutated ESKAPE superbugs, including multi-drug resistant (MDR) forms**
- Additional time kill concentration studies are underway with drug-resistant bacterial and are expected to be in-line with existing MIC/Time Kill.
- On-track to be the only clinical stage company shown to be efficacious against the full suit of **ESKAPE** pathogens globally
  - **Supported by R327's unique and multi-layered MoA**

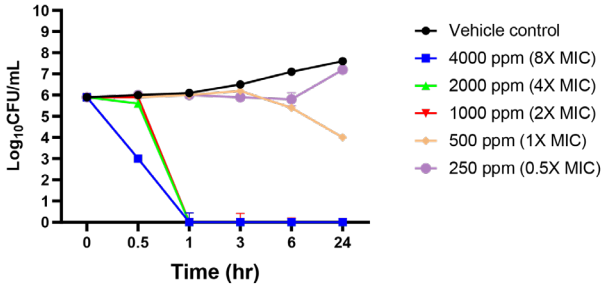


***Broad spectrum antibiotic efficacy** – **drug resistant** ESKAPE pathogens especially susceptible to R327 in comparison to standardised bacterial forms*

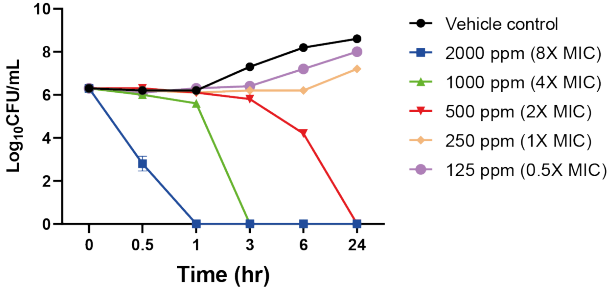
ESKAPE Pathogens Can't Escape R327

*On-track to be the only clinical stage company shown to be efficacious against the full suit of **ESKAPE** pathogens globally*

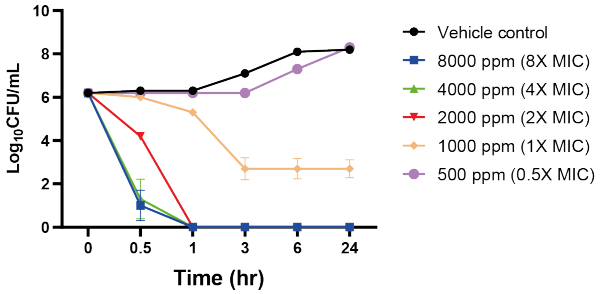
E. faecium **ATCC 19434 with RECCE® 327**
Time-kill curve (average)



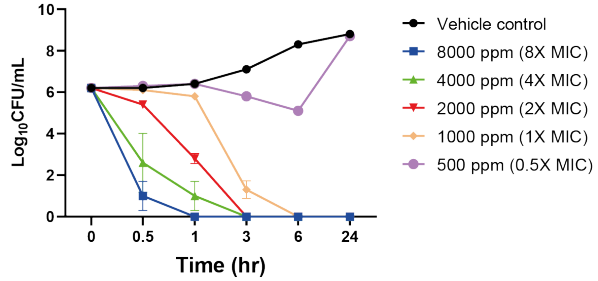
S. aureus **ATCC 29213 with RECCE® 327**
Time-kill curve (average)



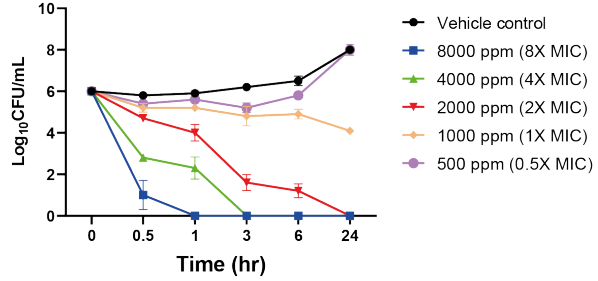
K. pneumoniae **ATCC 43816 with RECCE® 327**
Time-kill curve (average)



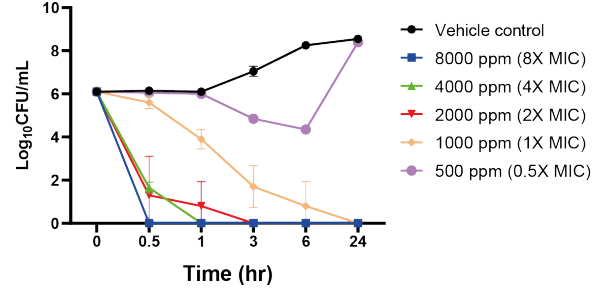
A. baumannii **ATCC 17978 with RECCE® 327**
Time-kill curve (average)



P. aeruginosa **ATCC 27853 with RECCE® 327**
Time-kill curve (average)



Enterobacter cloacae **ATCC 13047 with RECCE® 327**
Time-kill curve (average)



- ***Time-kill curves of R327 at various concentrations against strains of ESKAPE pathogens. In the time kill assay, each R327 dilution was tested in duplicate with the average plot shown.***
- The minimum inhibitory concentration was first determined to define the test concentrations for the time-kill study. The time-kill study was performed to determine the bacterial killing effect of R327 at a total of five concentrations, ranging from 0.5X to 8X, MIC and to measure killing kinetics of treatment with R327 against each strain.

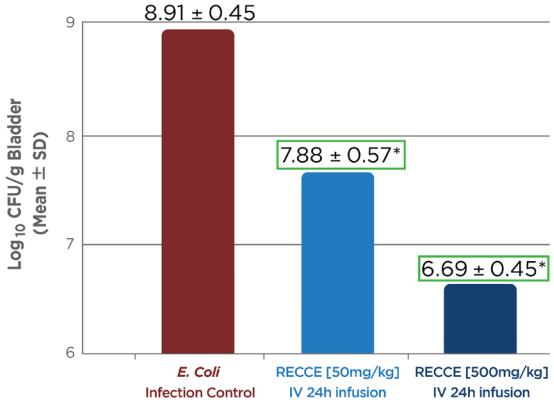
R435 Pre-clinical Studies

Further Pre-clinical Studies planned with R435 against *H. pylori*

- **Murdoch Children's Research Institute (MCRI) to evaluate *in-vivo* antimicrobial activity of R435 oral formulation against *H. pylori* in pre-clinical studies program**
- **Study led by *H. pylori* infectious disease expert Prof. Philip Sutton**
  - **Using mice as a highly validated animal model for *H. pylori***
- **MCRI is one of the top three children's 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 R435
- Anticipated completion at approximately mid-2022, at which time Recce may pursue a human clinical trial second half of 2022

Pre-sepsis UTI and Kidney Models in Mice

Efficacy: Bladder



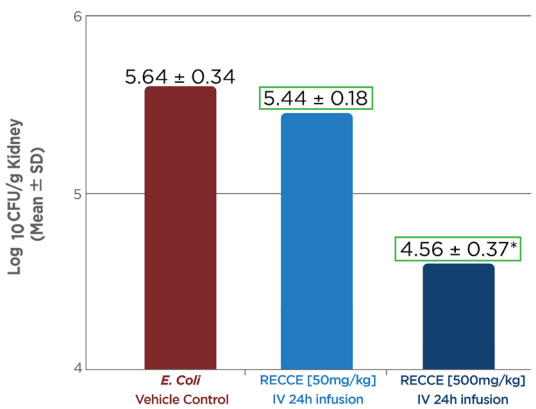
*(P<0.05) significantly different from vehicle control

Group 1 – **Bladder** *E. Coli* infection + vehicle control

Group 2 – **Bladder** *E. Coli* infection + R327 50mg/kg

Group 3 – **Bladder** *E. Coli* infection + R327 500mg/kg

Efficacy: Kidneys



*(P<0.05) significantly different from vehicle control

Group 1 – **Kidney** *E. Coli* infection + vehicle control

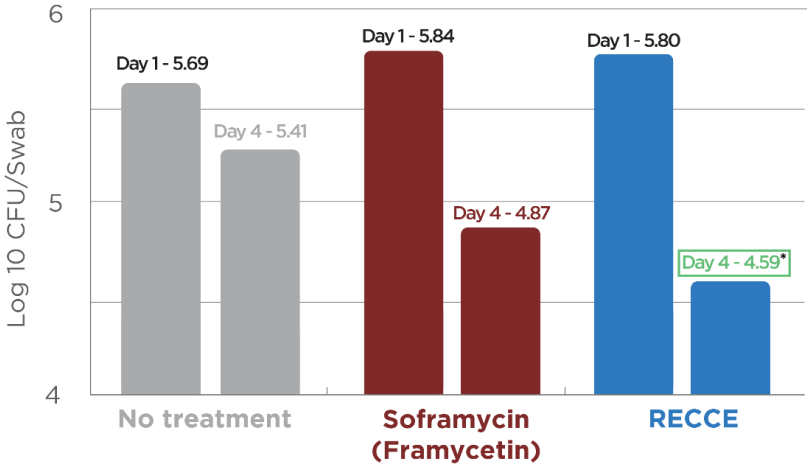
Group 2 – **Kidney** *E. Coli* infection + R327 50mg/kg

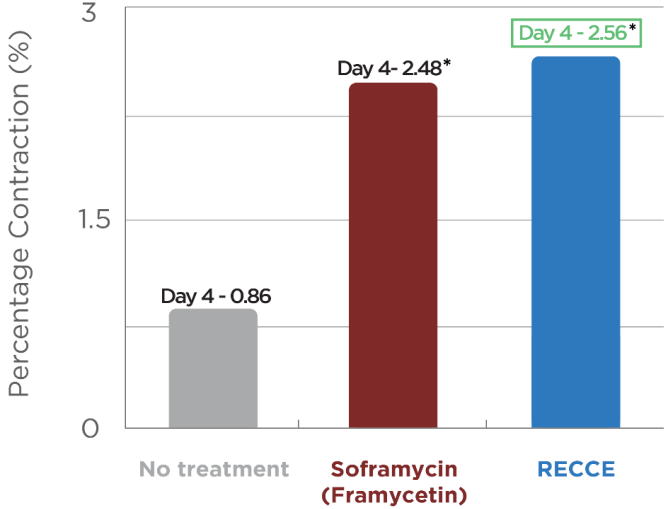
Group 3 – **Kidney** *E. Coli* infection + R327 500mg/kg

- Single 24-hour intravenous infusion.
- **R327 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)* in Rats





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..."*

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

Sepsis – it's a big problem!

48.9 million incident cases of **sepsis** recorded worldwide[1]

11 million sepsis related **deaths** recorded[2]

One in three patients who die in hospital have sepsis[3]

- Sepsis is a life-threatening inflammatory response to infection that has spread in the body.
  - Kills more people in the US than **prostate**, **breast cancer** 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]

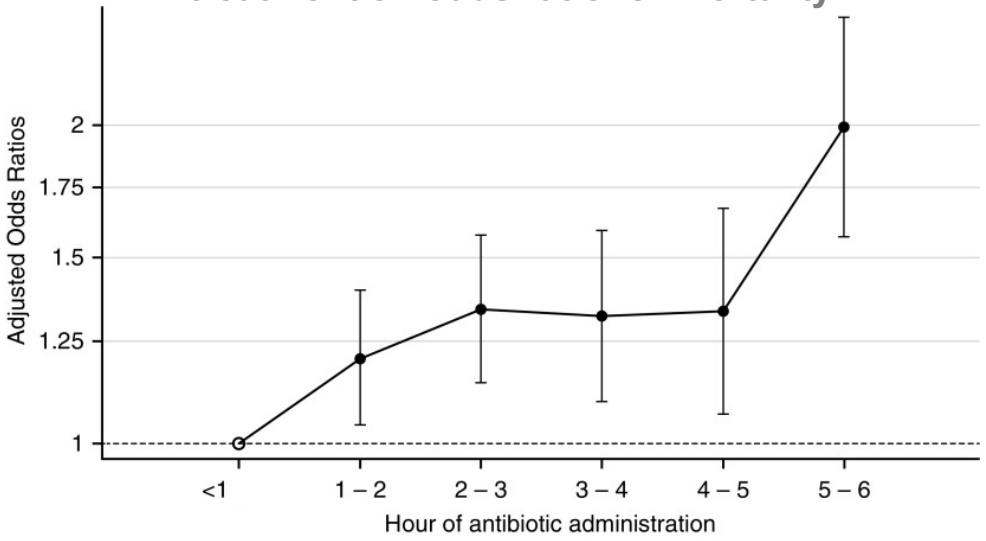
1,2,3 – The Lancet
4 – BioMed Central
5 – University of Texas
6 – International Medicine Journal RACP

Treatment Paradigm

- Current treatment paradigm relies on:
  - Introducing broad spectrum antibiotic(s);
  - Running antibiograms;
  - Adjusting antibiotics based on antibiogram results.

~1/3 of patients present unspecific symptoms, leading to delayed treatment and high mortality rate

Impact of delayed antibiotic treatment on odds ratio for mortality[1]



Early treatment with the correct antibiotic is key to patients' outcome.

Mortality from sepsis increases by as much as 8% for every hour that treatment is delayed[2]

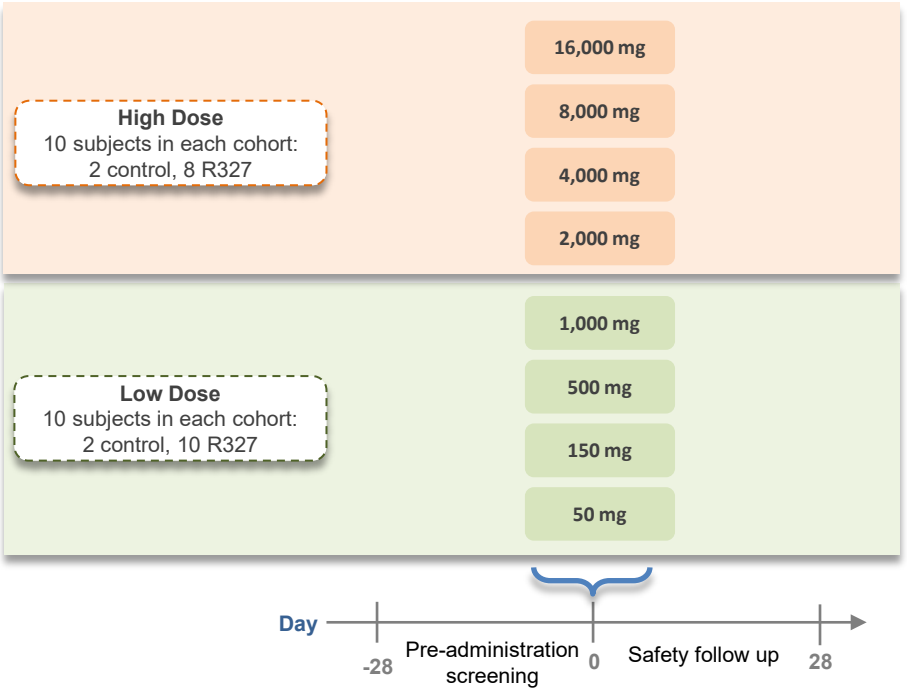
1 – Vincent X. Liu et al. The Timing of Early Antibiotics and Hospital Mortality in Sepsis - Am J Respir Crit Care Med. 2017 Oct 1; 196(7): 856–863

2 – https://www.sepsis.org/wp-content/uploads/2017/05/Sepsis-Fact-Sheet-2018.pdf

Phase I Human Clinical Trial

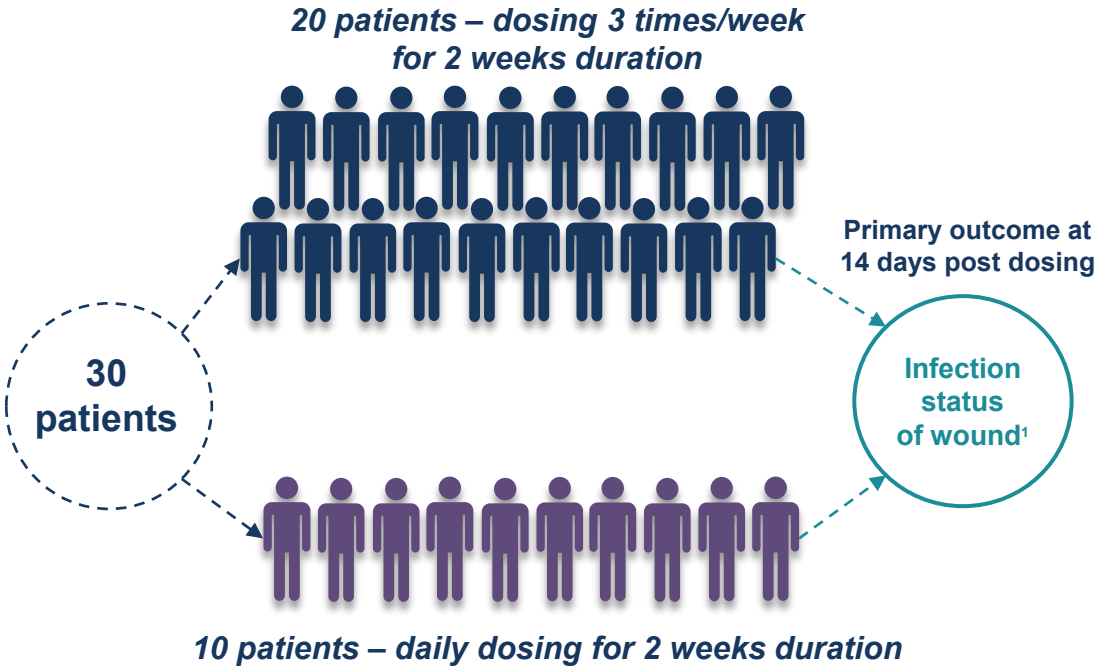
- **Study to assess IV infusion of R327 in 80 healthy male subjects as a single ascending dose.**
- Formal subject recruitment expected to open for enrolments shortly.
- Randomized, double blind, placebo controlled, safety, tolerability and pharmacokinetics study.
- Single dose of a 1-hour via IV infusion at a uniform rate in hospital setting.
- Primary endpoint: vital signs, 12-lead ECG parameters, clinical chemistry, hematology, and urinalysis.

Interim data expected late 2021
Full data expected H1-2022



Topical RECCE® 327 - Phase I/II

- **Phase I/II** to assess Topical R327 Topical in burn wound infections.
- Sponsored by the South Metropolitan Health Service, Department of Health, Government of Western Australia.
- **Multiple patients have been dosed with R327.**
- **Trial Investigators:**
  - Dr Edward Raby (Clinical Microbiologist and Infectious Diseases expert at Royal Perth and Fiona Stanley Hospitals);
  - Professor Fiona Wood (Head of Burns) – world-renowned burns specialist and spray-on skin pioneer;
  - Dr Chris Heath (Head of Infectious Diseases).
- Data expected in CY Q4 2021



1 - Using the consensus clinical criteria of the International Wound Infection Institute

Strong Pipeline

Over Various Indications and Upcoming Inflection Points

Asset Route of administration	Indications	Discovery	Preclinical	Phase I	Phase II	Phase III	Next data readout	Market Size
Anti-bacterial programs								
R327 **Intravenous & Intranasal**	Serious/life threatening bacterial infections including sepsis						Phase I interim data readout Q4 2021	47-50 million cases worldwide
	Pre-sepsis - kidney & UTI infections					To start post Phase II in sepsis		
R327 **Topical**	Wound infections including infected burns						Phase I/II Data CY Q4 2021	11 million burn wound cases requiring medical intervention. Majority of which escalate to infection
R435 **Oral R529**	*Helicobacter pylori* in stomach ulcers							Up to 4.4 billion worldwide
Anti-viral programs								
R327 **Nasal**	COVID & Influenza							
R529 **IV and Intranasal**	COVID							

IP, Regulatory and Market Access

Recce's patent portfolio includes more than 20 issued patents and patent applications in the world's major markets, including the United States, Europe, Japan, China and Australia.

Filed	Patent Family 1	Expiry	Patent Family 2	Expiry	Patent Family 3	Expiry
Australia	✓	2028	✓	2035	Pending	2037
USA	✓	2029	✓	2035	✓	2037
Europe	✓	2028	✓	2035	✓	2037
Japan	✓	2028	✓	2035	✓	2037
China	✓	2028	Pending	2035	✓	2037

✓ Granted

Patent Family 1 – Antimicrobial Polymers and their Compositions.

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

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

*The FDA has awarded R327 **Qualified Infectious Disease Product** designation for bacteriemia (G+/G-) under the **Generating Antibiotic Initiatives Now (GAIN) Act** – labelling it for **Fast Track Designation**, plus **10 years of market exclusivity post approval.***

Insourced Manufacturing Capabilities

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 hour.**
- **500 doses** per fully automated 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' standards.

Empowering Clinicians with a New Class of Antibiotics

The need for new antibiotics has never been greater

- **Initial resistance to use** new approved drugs due to antibiotic resistance
- "**New antibiotics**, able to kill drug-resistant bacteria, is **essential** to saving modern medicine."
  - *Wellcome Trust*
- "**Lack** of **new antibiotics threatens** global efforts to contain drug-resistant infections."
  - *World Health Organization*

R327 addressing market need

- **R327 does not contribute to AMR**, supported by unique and multi-layered MoA.
  - **Empowering clinicians** to **confidently** and **quickly administer R327** at first patient presentation.
- Use of R327 may **alleviate the selective pressure on bacteria posed by other antibiotics** and allow them to regain efficacy.

Physician perspectives on R327

"We have so few options when patients have difficult pathogens. This agent would be great to come into play for them." – ID KOL

"This may start off being used in resistant patients, but if it is really compelling, of course physicians will use it for more people." – Pulm. KOL

"If a patient has M. abscessus, they're fortunate if they get any improvement, and there's sometimes potentially permanent damage." – Pulm. KOL

MDR: Multidrug Resistant; ROA: Route of Administration; IV: Intravenous; MOA: Mechanism of Action; KOL: Key Opinion Leaders. Source: Physician Interviews; Clearview Analysis.


Recce
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Thank you

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