



Corporate Presentation

LifeSci Corporate Access Event 2023

41st Annual J.P. Morgan Health Care Conference

[recce.com.au](https://www.recce.com.au)
ASX:RCE FSE:R9Q

January 2023

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Board Structure



Dr John Prendergast
Executive Chairman
(Shares: 250,000)
(Options: 2,175,000)



James Graham
Chief Executive Officer
(Shares: 6,031,932 – 3.39%)
(Options: 2,250,000)



Michele Dilizia
Chief Scientific Officer
(Shares: 3,543,485 – 2.0%)
(Options: 1,500,000)



Justin Ward
Executive Director &
Principal Quality Chemist
(Shares: 158,966)
(Options: 600,000)



Alistair McKeough
Non-Executive Director
(Shares: 25,000)
(Options: 1,125,000)



Dr Alan Dunton
Non-Executive Director
(Shares: 60,000)
(Options: 1,125,000)



Justin Reynolds
Outsourced CFO



Maggie Niewidok
Company Secretary



A Versatile Technology Platform

- Biotech company developing **Anti-infectives** targeting both bacterial and viral indications
- **Strong IP** and **own manufacturing** capability
- Qualified Infectious Disease Product designation
 - 10 years market exclusivity plus fast track approval*
- **Versatile delivery platform** – oral, intravenous and topical formulations
- Designed to safely provide treatment **without developing resistance** over time
- Multiple infectious disease opportunities with RECCE® 327



Sepsis – it's a big problem!

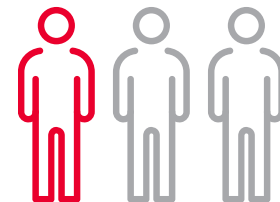
48.9 million incident cases of **sepsis** recorded worldwide¹



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 cancer** and **HIV/AIDS** combined⁴.
- Is the **most expensive condition to treat** in the last 8 years⁵.
 - **Double the average cost per stay across all other conditions**⁵.
- Currently no drug therapies specifically for the treatment of sepsis⁶.



Sepsis Patient Journey



Patient Presents at the Hospital

- 1/3 of patients present non-specific symptoms, leading to delayed treatment and high mortality rate.
- Mortality from **sepsis** increases by as much as 8% for every hour that treatment is delayed.
- Cost of **sepsis** care for inpatient admissions and skilled nursing facility: in-patient rehab medical treatment centre admissions was more than USD \$62bn/year (USD \$170m/day).

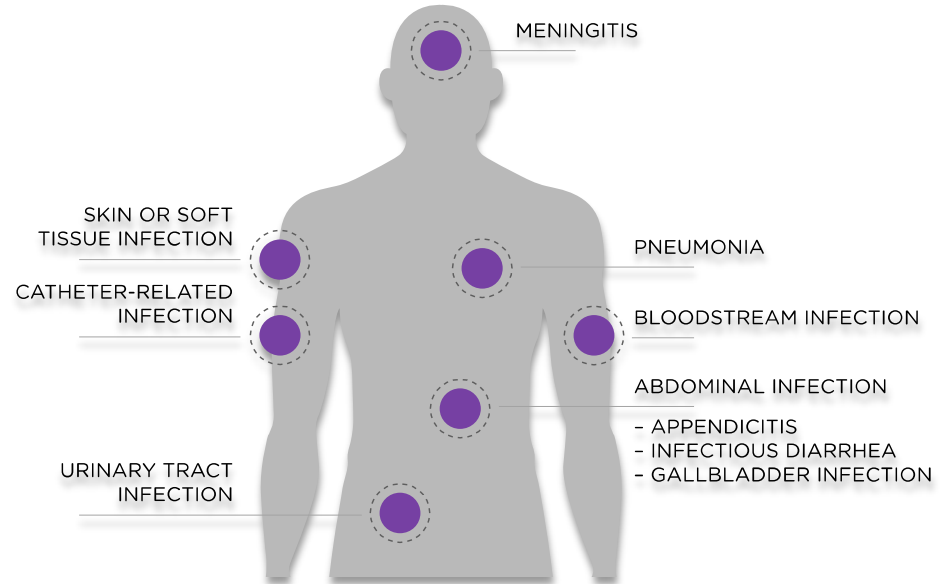


Current Treatment Paradigm

- Introducing broad-spectrum antibiotic (s)
- Running antibiograms
- Adjusting antibiotics based on antibiogram results



Early treatment with the correct antibiotic is key to improving patient outcome



The Need for a New Class of Antibiotics: Synthetic Anti-Infectives



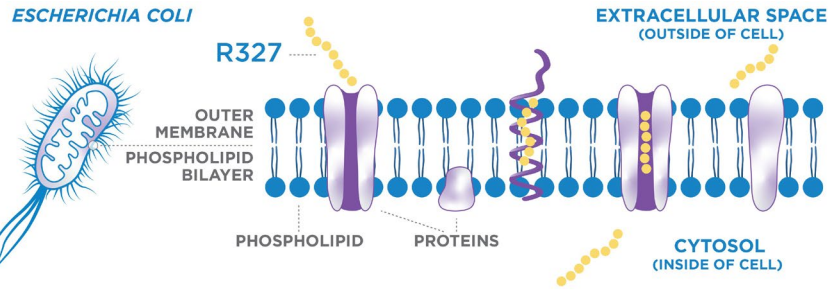
- **NO** pre-formed natural superbugs.
- Entirely **man-made** and designed with purpose.
- **Universal Mechanism of Action** - does not succumb to resistance.
- **Broad Spectrum capability** and maintains its activity even with repeated use.
- **Empowers clinicians** to confidently and quickly administer an effective antibiotic at first patient presentation.
- On-track to be the only **global clinical stage company** whose drug is shown to be **efficacious** against the full suite of **ESKAPE pathogens**.



Independent Study Undertaken on R327 MoA¹

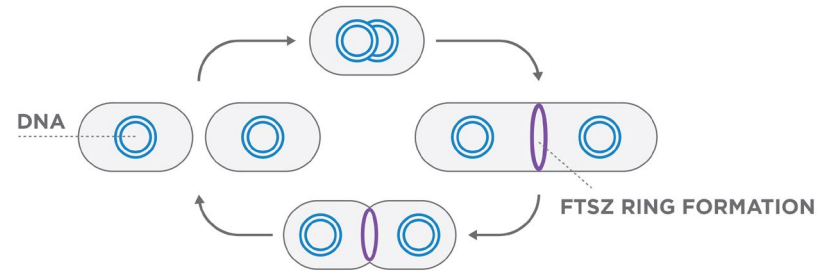
By Leading Experts in Bacterial MoA Analysis

Stage 1



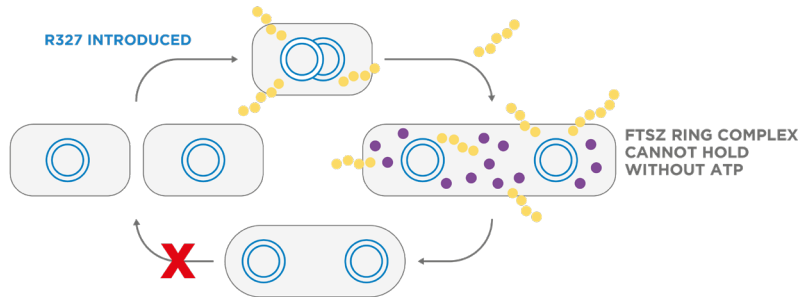
R327 permeabilizes cell membrane and enters the cell

Stage 2



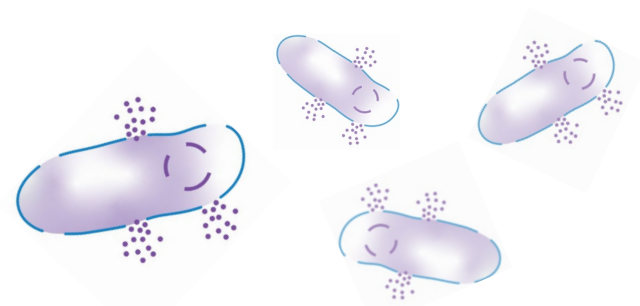
R327 interrupts bacterial cellular energetics via ATP Synthesis

Stage 3



Cellular division & non-dividing cell functions are disrupted

Stage 4



R327 is rapidly and irreversibly bactericidal - at high concentrations causes cell lysis

RECCE[®] 327 Multi-Layered Mechanism of Action¹



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 ($>1 \times 10^7$ to 1×10^5 at timepoint 0).



Current antibiotics rarely retain 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 Activity Against *Escherichia coli*

- *E. coli* grows fast.
Eukaryotic cells healthy and not affected.
- R327 at 3,000 ppm shown to be highly effective against *E. coli* without affecting growing, healthy eukaryotic cells.
- R327 rapidly and irreversibly shuts down the ATP in *E. coli*, not allowing it to divide and grow.

Without R327



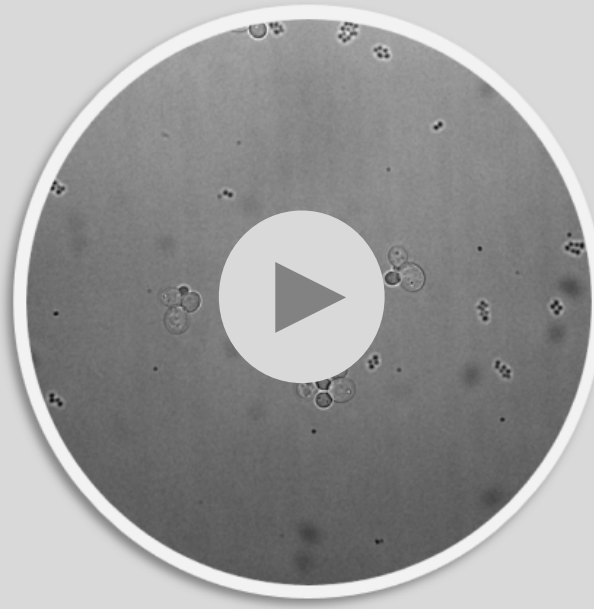
R327 (3,000 ppm)



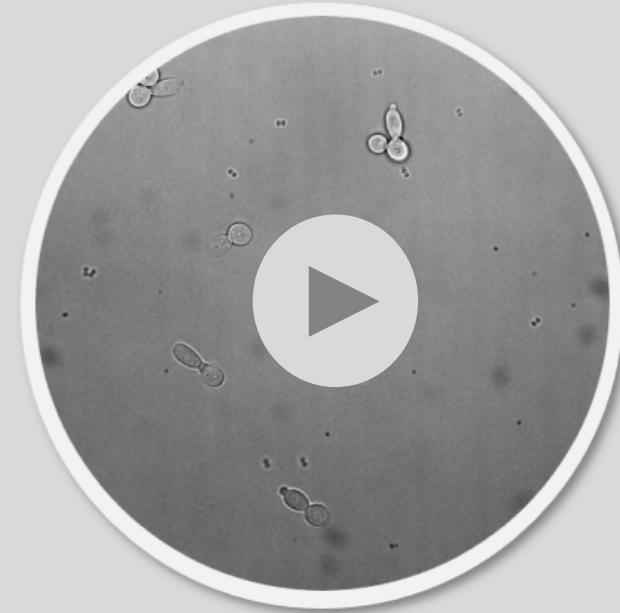
RECCE[®] 327 Activity Against *Staphylococcus aureus*

- *S. aureus* bacterial growth slower than *E. coli*, not affecting eukaryotic cells.
- **R327 at 2,300 ppm** shows to be highly effective against *S. aureus* without affecting growing, healthy eukaryotic cells.
- **R327 rapidly and irreversibly shuts down the ATP** in *S. aureus*, not allowing it to divide and grow.

Without R327



R327 (2,300 ppm)

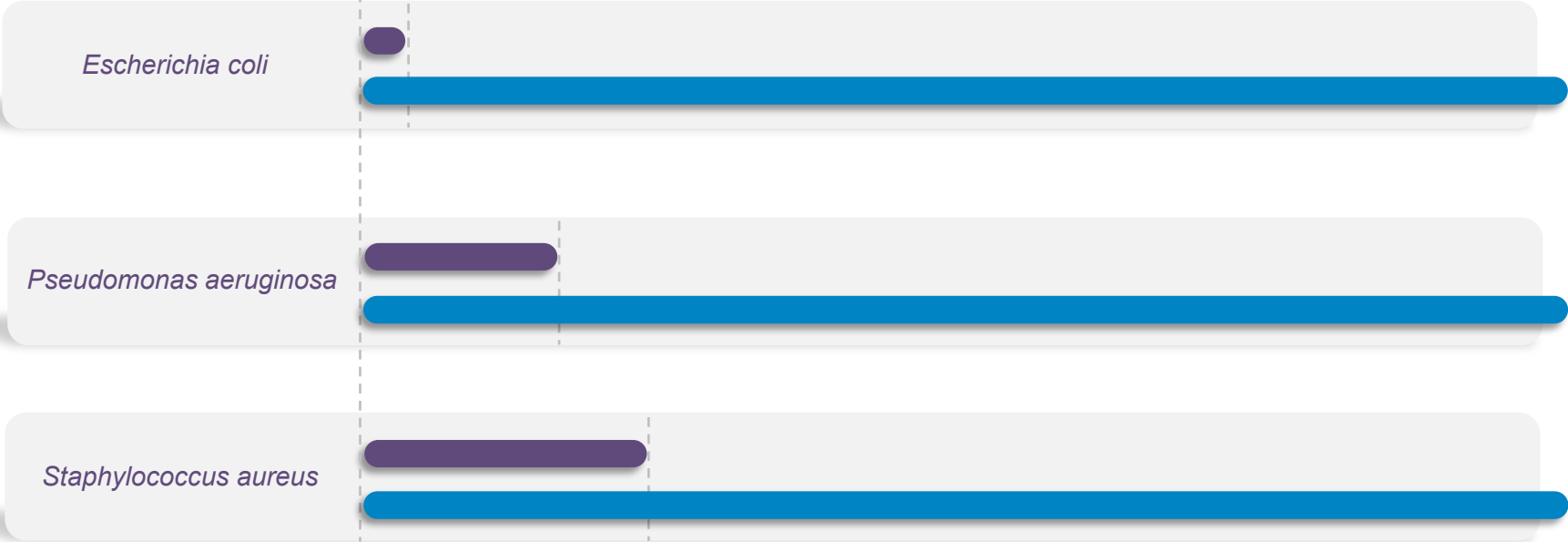


RECCE® 327 Maintains Activity¹

Number of repeats before displaying loss of antibiotic activity

Bacteria

2 4 6 8 10 12 14 16 18 20 22 24 25 →

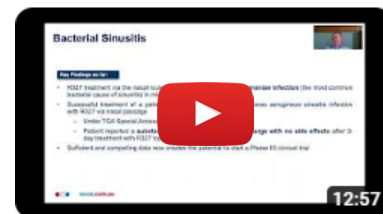


The commercial antibiotic loses activity after a number of repeats; >25 repeats RECCE® 327 **DOES NOT**

● 'Commercial Antibiotic' generates over US \$10bn in revenue ● RECCE® 327

Pre-Clinical Study Outlook

- **Recce's new Anti-Infective Research (AIR) Unit: Fit-for-purpose laboratory space**
 - Located within Murdoch Children's Research Institute
 - Recce will streamline ongoing pre-clinical programs and explore new research development opportunities
 - Dedicated Murdoch Children's team with access to infectious disease and other expertise
- **Mechanism of Action studies**
 - Results confirm that R327 is broad spectrum, bactericidal, effective against growing and non-growing cells
- **R327 COVID Animal Study (Netherlands)**
 - R327 was shown to significantly reduce SARS-CoV-2 levels in the throat in a dose-dependent manner



Dr Philip Sutton's Pre-Clinical Update

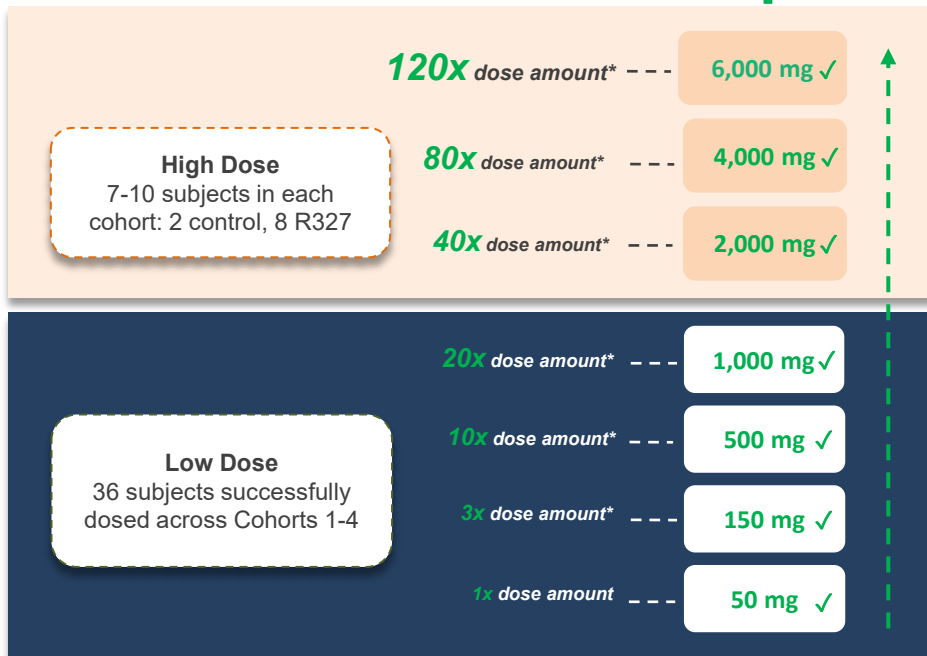
Asset and Route of Administration	Indications	Discovery	Pre-Clinical	Phase I	Phase II
RCE Compounds*	<i>Mycobacterium abscessus</i> pre-clinical program	[Progress bar in Pre-Clinical phase]			
	Bacterial Sinusitis pre-clinical program	[Progress bar in Pre-Clinical phase]			
	Additional TBA pre-clinical program	[Progress bar in Pre-Clinical phase]			



Phase I Human Clinical Trial

- Study to assess IV infusion of RECCE[®] 327 in healthy male subjects as a single ascending dose.
- 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.

Complete



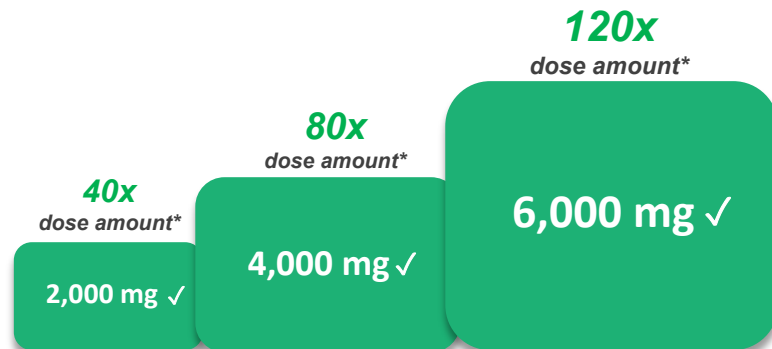
*Dose increase fold based off 50mg



Phase I Human Clinical Trial – ‘High Dose’

Why 6,000mg (R327) over 1 hour infusion?

- Study objectives **achieved** – Phase II preparations are underway
- **R327 dosing broadly in efficacy range** based on animal models – Phase II (efficacy) to determine.
- Phase I (IV Safety/Tolerability) data sets opportunity for multiple Phase II (efficacy) study potential.
- **Data unblinding complete and packaging submission to TGA including request for publication – Q1 2023**

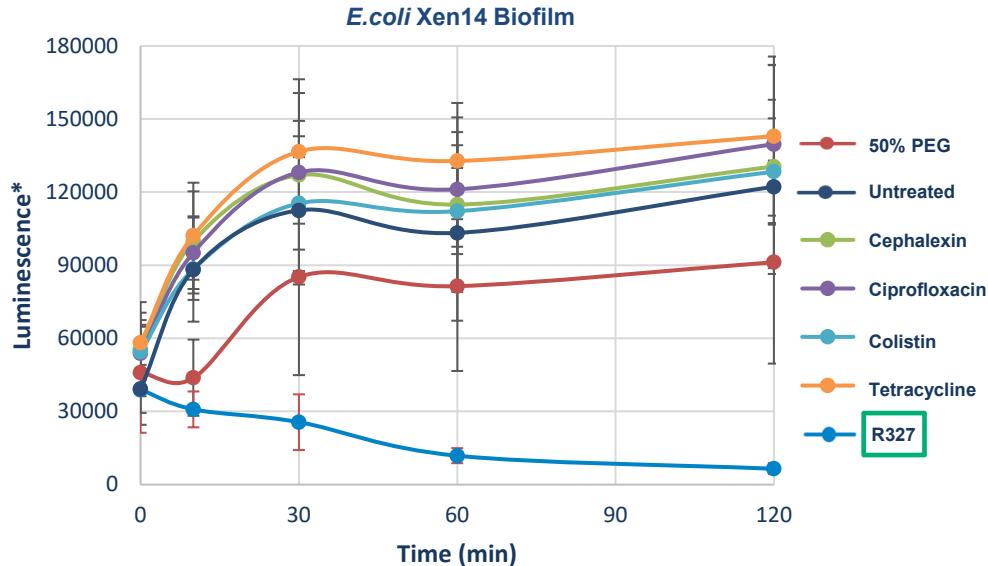


*As a result of **Phase I achievements**,
Phase II preparations are underway in
UTI, Kidney Infection Urosepsis and Sepsis*

*Dose increase fold based off 50mg



R327 faster acting than existing antibiotics – no prolonged exposure needed



- R327 kills pathogenic bacteria at a faster rate.
- R327 designed to work faster than all existing antibiotics, reinforced by MoA work undertaken by experts in their field.

“R327 kills bacteria in conditions where other antibiotics are ineffective.”

- Marc Sharp, PhD, Chief Scientific Officer, Linnaeus Bioscience

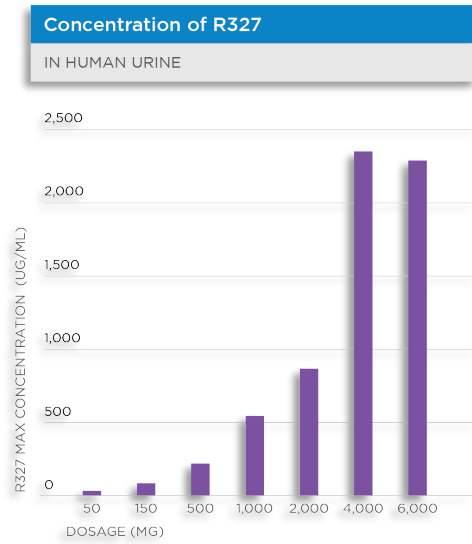
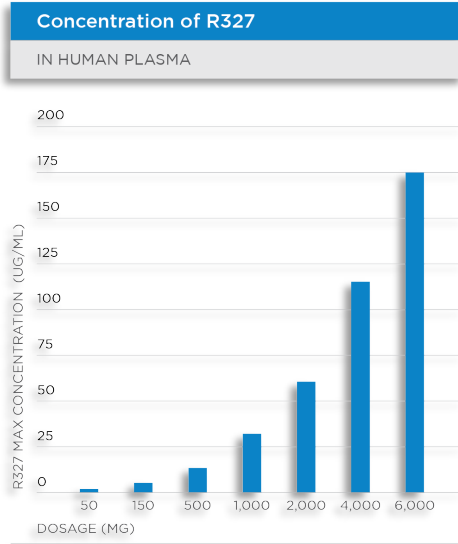
R327 is faster-acting against bacteria than other antibiotics – works quickly, without prolonged cellular exposure times required of other antibiotics (extended exposures commonly associated with systemic toxicity).



Reason for Optimism in Treating UTI/Sepsis



Dr Alan Dunton's Clinical Update



Concentration of R327 in Urine Compared to Plasma

In over 60 healthy subjects

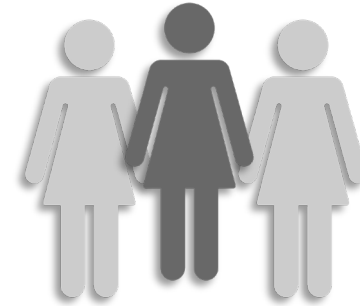
Ratio Urine/Plasma -
15x
13x
15x
17x
14x
20x
13x

- **R327 primary route of elimination** appears to be through the kidney to the ureters and bladder.
- **High concentrations of R327** noted in the urine of Phase I healthy subjects.
- **Insight consistent** with pre-clinical *in-vivo* kidney and UTI bacterial infection studies.

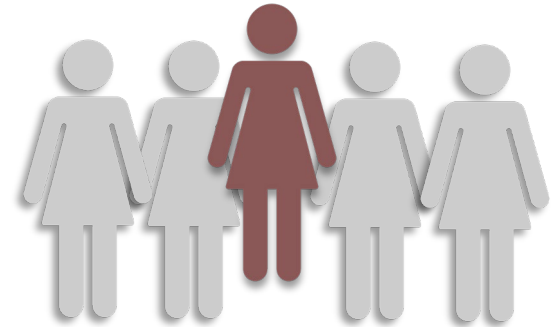
- **Opportunities for therapeutic** in array of UTIs (uncomplicated UTI - single dose, complicated UTI, recurrent UTI, treatment resistant etc).
- Suggests **broader anti-infective treatment model** in pre-sepsis.

Background on UTIs

- **Urinary tract infection (UTI) is one of the most common infectious diseases**
- The most common pathogen causing UTIs is *Escherichia coli* (*E. coli*) with 62%
 - The **resistance** among the **isolates of *E. coli*** are: ampicillin (86%), amoxicillin (76%), tetracycline (71%), trimethoprim-sulfamethoxazole (64%), cephalexin (61%), and cefalothin (60%)
- **Globally, more than 404.6 million individuals had UTIs in 2019**
 - USD \$6 billion dollars in direct health care expenditure
 - Previous years have demonstrated the likelihood of antibiotics killing most UTIs is rapidly dropping



One in three uncomplicated UTIs in young healthy women are Bactrim-resistant



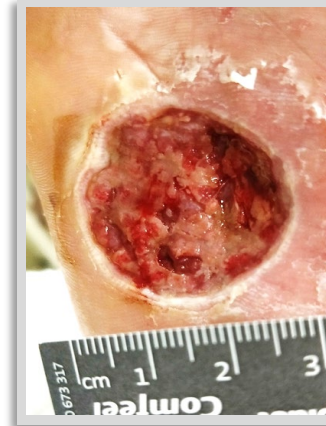
One in five are resistant to five other common antibiotics.



Topical RECCE® 327 – Phase I/II

Patient examples from ongoing Burn Wound trial

- Patients suffered major burn injury.
- Multiple bacterial species in and surrounding wound.
- Growth swabs with organisms including pathogens from the ESKAPE group of bacteria.
- **Post R327 treatment: healthy skin growth return, reduced swelling and infection, indications of tissue penetration to underlying infection.**
- Building upon the success of these results, the Company has built out its topical treatment programs to include a new Phase II clinical study for Diabetic Foot Ulcer infections.
- *Domestic and International interest in study and study site expansion progressing, with expected advancement Q1 2023*



Pre-treatment, significant
bacterial infection



Post R327 **treatment**



Phase I/II Diabetic Foot Ulcer (DFU) Clinical Trial



Clinical Trial Overview

- **Human Research Ethics approval received**
- Phase I/II to assess safety and efficacy of R327 on mild skin and soft tissue diabetic foot infections.
- Clinical trial to start at **South West Sydney Limb Preservation and Wound Research Unit**, located at the **Ingham Institute of Medical Research**.
- Unit selected for its **innovative** and **ground-breaking focus** on wounds of the limbs and limb loss, an **under-researched area** in Australian healthcare.



Market Opportunity

- The total **medical cost** for treating diabetic foot diseases in the United States is **US \$9-13 billion every year¹**.
- Studies in the US have shown between **14-24% percent of patients with diabetes** who develop a **foot ulcer** will **require an amputation**, and foot ulceration precedes **85% of diabetes-related amputations²**.
- **Sydney's South West** also has one of the **highest prevalence rates of diabetes in NSW** and complications from this disease can significantly impact people's quality of life.



Patents

Four families across all major markets

Filed	Patent Family 1	Expiry	Patent Family 2	Expiry	Patent Family 3	Expiry
Australia	✓	2028	✓	2037	Accepted	2037
USA	✓	2029	✓	2037	✓	2037
Europe	✓	2028	✓	2037	✓	2037
Germany	✓	2028	✓	2037	✓	2037
Spain	✓	2028	✓	2037	✓	2037
France	✓	2029	✓	2037	✓	2037
UK	✓	2028	✓	2037	✓	2037
Italy	✓	2028	✓	2037	✓	2037
Sweden	✓	2028	✓	2037	✓	2037
Japan	✓	2028	✓	2037	✓	2037
China	✓	2028	Pending	2037	✓	2037
HK	Pending	2028	Pending	2037	✓	2037

Family 1 group relates to the Company's Unique and Highly Economical Manufacturing Process and use of the Polymer in Treatment of Diseases.

Family 2 relates to the Method of Manufacture, Administration and Application to Treat a Broad Range of Common Human Infections.

Family 3 relates to a Method of Treatment of a Broad Range of Viral Infections, particularly Parenteral Viral Infection.

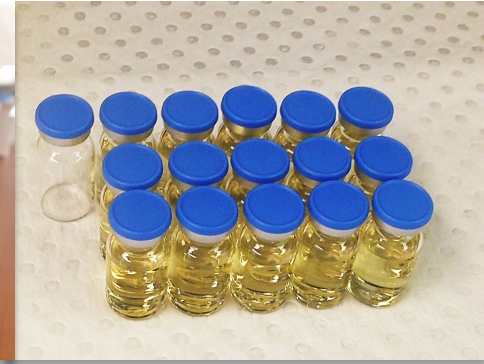
Recce's patent portfolio contains over 40 patents and patent applications in the world's major markets.

Country	Title	Case_Status	Grant_Date	Applicant	Family
Australia	ANTI-MICROBIAL POLYMERS AND THEIR COMPOSITIONS	Granted	25/08/2011	Recce Pharmaceuticals Ltd	Family 1
China	ANTI-MICROBIAL POLYMERS AND THEIR COMPOSITIONS	Granted	25/11/2015	Recce Pharmaceuticals Ltd	Family 1
France	ANTI-MICROBIAL POLYMERS AND THEIR COMPOSITIONS	Granted	7/10/2015	Recce Pharmaceuticals Ltd	Family 1
Germany	ANTI-MICROBIAL POLYMERS AND THEIR COMPOSITIONS	Granted	7/10/2015	Recce Pharmaceuticals Ltd	Family 1
Italy	ANTI-MICROBIAL POLYMERS AND THEIR COMPOSITIONS	Granted	7/10/2015	Recce Pharmaceuticals Ltd	Family 1
Japan	ANTI-MICROBIAL POLYMERS AND THEIR COMPOSITIONS	Granted	3/10/2014	Recce Pharmaceuticals Ltd	Family 1
Spain	ANTI-MICROBIAL POLYMERS AND THEIR COMPOSITIONS	Granted	7/10/2015	Recce Pharmaceuticals Ltd	Family 1
Sweden	ANTI-MICROBIAL POLYMERS AND THEIR COMPOSITIONS	Granted	7/10/2015	Recce Pharmaceuticals Ltd	Family 1
UK	ANTI-MICROBIAL POLYMERS AND THEIR COMPOSITIONS	Granted	7/10/2015	Recce Pharmaceuticals Ltd	Family 1
USA	ANTI-MICROBIAL POLYMERS AND THEIR COMPOSITIONS	Granted	1/09/2015	Recce Pharmaceuticals Ltd	Family 1
Australia	COPOLYMER AND METHOD FOR TREATMENT OF BACTERIAL INFECTION	Granted	8/11/2018	Recce Pharmaceuticals Ltd	Family 2
China	COPOLYMER AND METHOD FOR TREATMENT OF BACTERIAL INFECTION	Response Lodged		Recce Pharmaceuticals Ltd	Family 2
France	COPOLYMER AND METHOD FOR TREATMENT OF BACTERIAL INFECTION	Granted	28/08/2019	Recce Pharmaceuticals Ltd	Family 2
Germany	COPOLYMER AND METHOD FOR TREATMENT OF BACTERIAL INFECTION	Granted	28/08/2019	Recce Pharmaceuticals Ltd	Family 2
Italy	COPOLYMER AND METHOD FOR TREATMENT OF BACTERIAL INFECTION	Granted	28/08/2019	Recce Pharmaceuticals Ltd	Family 2
Japan	COPOLYMER AND METHOD FOR TREATMENT OF BACTERIAL INFECTION	Granted	25/10/2019	Recce Pharmaceuticals Ltd	Family 2
Spain	COPOLYMER AND METHOD FOR TREATMENT OF BACTERIAL INFECTION	Granted	28/08/2019	Recce Pharmaceuticals Ltd	Family 2
Sweden	COPOLYMER AND METHOD FOR TREATMENT OF BACTERIAL INFECTION	Granted	28/08/2019	Recce Pharmaceuticals Ltd	Family 2
UK	COPOLYMER AND METHOD FOR TREATMENT OF BACTERIAL INFECTION	Granted	28/08/2019	Recce Pharmaceuticals Ltd	Family 2
USA	COPOLYMER AND METHOD FOR TREATMENT OF BACTERIAL INFECTION	Granted	12/03/2019	Recce Pharmaceuticals Ltd	Family 2
Australia	ANTI-VIRUS AGENT AND METHOD FOR TREATMENT OF VIRAL INFECTION	Accepted		Recce Pharmaceuticals Ltd	Family 3
China	ANTI-VIRUS AGENT AND METHOD FOR TREATMENT OF VIRAL INFECTION	Granted	22/06/2021	Recce Pharmaceuticals Ltd	Family 3
France	ANTI-VIRUS AGENT AND METHOD FOR TREATMENT OF VIRAL INFECTION	Granted	21/04/2021	Recce Pharmaceuticals Ltd	Family 3
Germany	ANTI-VIRUS AGENT AND METHOD FOR TREATMENT OF VIRAL INFECTION	Granted	21/04/2021	Recce Pharmaceuticals Ltd	Family 3
Hong Kong	ANTI-VIRUS AGENT AND METHOD FOR TREATMENT OF VIRAL INFECTION	Granted	25/02/2022	Recce Pharmaceuticals Ltd	Family 3
Italy	ANTI-VIRUS AGENT AND METHOD FOR TREATMENT OF VIRAL INFECTION	Granted	21/04/2021	Recce Pharmaceuticals Ltd	Family 3
Japan	ANTI-VIRUS AGENT AND METHOD FOR TREATMENT OF VIRAL INFECTION	Granted	18/12/2020	Recce Pharmaceuticals Ltd	Family 3
Spain	ANTI-VIRUS AGENT AND METHOD FOR TREATMENT OF VIRAL INFECTION	Granted	21/04/2021	Recce Pharmaceuticals Ltd	Family 3
Sweden	ANTI-VIRUS AGENT AND METHOD FOR TREATMENT OF VIRAL INFECTION	Granted	21/04/2021	Recce Pharmaceuticals Ltd	Family 3
United Kingdom	ANTI-VIRUS AGENT AND METHOD FOR TREATMENT OF VIRAL INFECTION	Granted	21/04/2021	Recce Pharmaceuticals Ltd	Family 3
USA	ANTI-VIRUS AGENT AND METHOD FOR TREATMENT OF VIRAL INFECTION	Granted	29/06/2021	Recce Pharmaceuticals Ltd	Family 3
USA	ANTI-VIRUS AGENT AND METHOD FOR TREATMENT OF VIRAL INFECTION	Filed		Recce Pharmaceuticals Ltd	Family 3

In-house Manufacturing Capabilities

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 approx. 1 hour
- 500 doses per fully automated run
- Quality and Quantity demonstrated capability to support present and future human clinical trials.
- Facility built to pharmaceutical specification.
- Packaging and labelling to international standards



Recce Pharmaceuticals Ltd – Capital Structure

Snapshot

Tickers ASX:RCE, FSE:R9Q

Market Cap (approx.) **USD \$78.96 million****
Priced at AUD \$0.65/share

Cash and deposits* **USD \$3.93 million****
28 October 2022

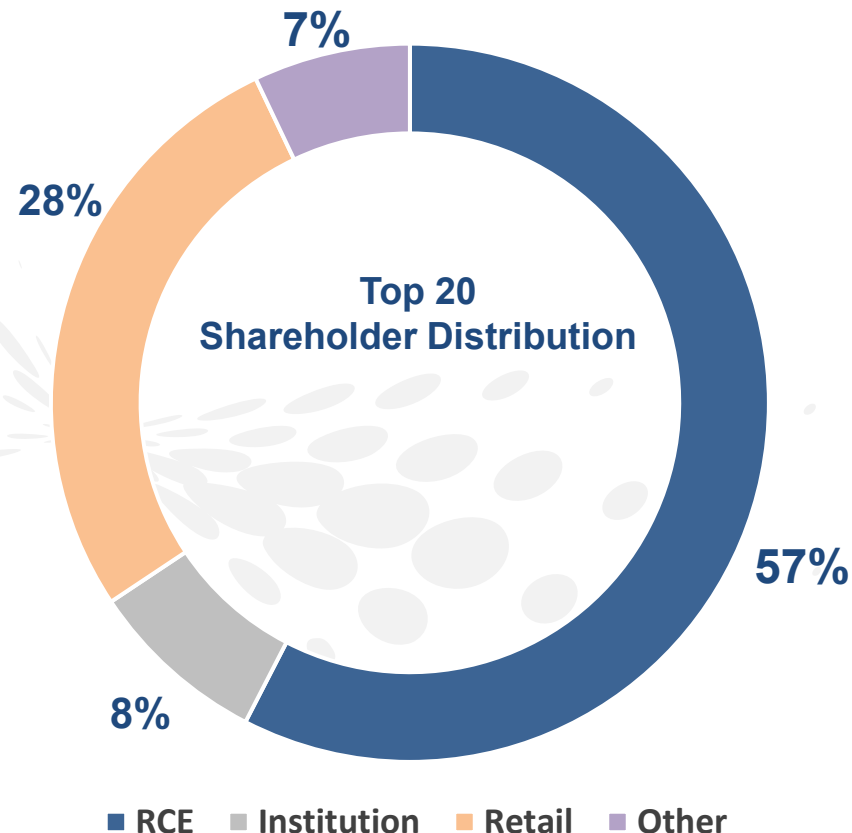
Outstanding shares **178.08 million**

Average daily volume **82.41k**
3 months

Debt **Nil**

****Converted 8 January 2023, 1 AUD = 0.68 USD**

***Pre > USD \$2.9m R&D rebate + other non-dilutionary cash in-flows expected this quarter - actual cash runway circa USD \$6.9 million**



Upcoming Clinical Milestones

- **In-vivo pre-clinical**
 - Pre-Sepsis UTI Models in Rats ✓
- **Phase I clinical trials**
 - R327 I.V. Single Dose, Safety/Tolerability/PK study in healthy subjects ✓
- **Phase II UTI clinical trial (Pre-Sepsis)**
 - Single (as now completed Phase I) efficacy study – Q1 2023
 - Multiple-dose treatment of UTIs - complicated/resistant/chronic/etc. H1 2023
- **Phase Ib/Ila Sepsis clinical trial**
 - R327 I.V. Multiple Dose, Safety/Tolerability/PK study in healthy subjects (First patient dosing H1 2023)
 - Multiple-Dose efficacy study in **urosepsis*** (sepsis derived from UTI infections) – efficacy signal
- **Phase II Diabetic Foot Ulcer (DFU) clinical trial**
 - R327 as a spray-on (topical) broad-spectrum antibiotic for mild skin and soft tissue DFU (First patient dosing expected Q1 2023)



Michele Dilizia Scientific Strategy Update



Summary



Proprietary **new class of anti-infectives** against bacteria and viruses, protected by Composition of Matter Patent.



Fast development plans initially targeting: **Sepsis, UTI, Burn wounds, Diabetic Foot Ulcers, COVID-19** and a suite of pre-clinical indications.



Strong pre-clinical data package demonstrating **high bactericidal activity** combined with **very good safety** at expected human therapeutic range.



State of the Art manufacturing capacities ensuring **highly attractive manufacturing costs and scalability**.



Multiple Phase I, Phase II and Phase III clinical programs, addressing unmet medical needs



Thank you

James Graham

Managing Director and Chief Executive Officer

Recce Pharmaceuticals Ltd

ASX:RCE; FSE:R9Q

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