

## ASX Announcement

### Spark Plus Healthcare Day Investor Presentation

**SYDNEY Australia, 3 November 2022:** Recce Pharmaceuticals Ltd (**ASX:RCE, FSE:R9Q**) (the **Company**), the Company developing a New Class of Synthetic Anti-infectives, is pleased to confirm its participation in Spark Plus's Healthcare Day on Thursday, 3 November 2022. The event will be presented live via Zoom with a Q&A opportunity following a 15-minute presentation.

The event will be held online via Zoom on **3<sup>rd</sup> November, Thursday at 5:45PM AEDT**

Please register using the link below:

[https://us02web.zoom.us/webinar/register/3016662416846/WN\\_hg\\_zogpnRRuems\\_eUjfr\\_A](https://us02web.zoom.us/webinar/register/3016662416846/WN_hg_zogpnRRuems_eUjfr_A)



A copy of the presentation slides can be found below

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



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**Washington Office:** 1717 Pennsylvania Avenue NW, Suite 1025, WASHINGTON DC 20006 USA

# Corporate Presentation

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Spark Plus Healthcare Day 2022

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# Management Structure



**Dr John Prendergast – Executive Chairman**

*BSc (Hons), MSc (UNSW), PhD (UNSW), CSS (HU)*

US based, current Chairman and Co-founder of Palatin Technologies, Inc. (NYSE: PTN) and Lead Director of Heat Biologics, Inc. (NASDAQ: HTBX) – extensive experience in the international commercialisation of pharmaceutical technologies.



**James Graham – Chief Executive Officer**

*BCom (Entrepreneurship), GAICD*

5 years as former Executive Director at RCE. Invested alongside shareholders in most capital rounds since inception. Background in marketing, business development and commercialisation of early-stage technologies.



**Michele Dilizia – Chief Scientific Officer**

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

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



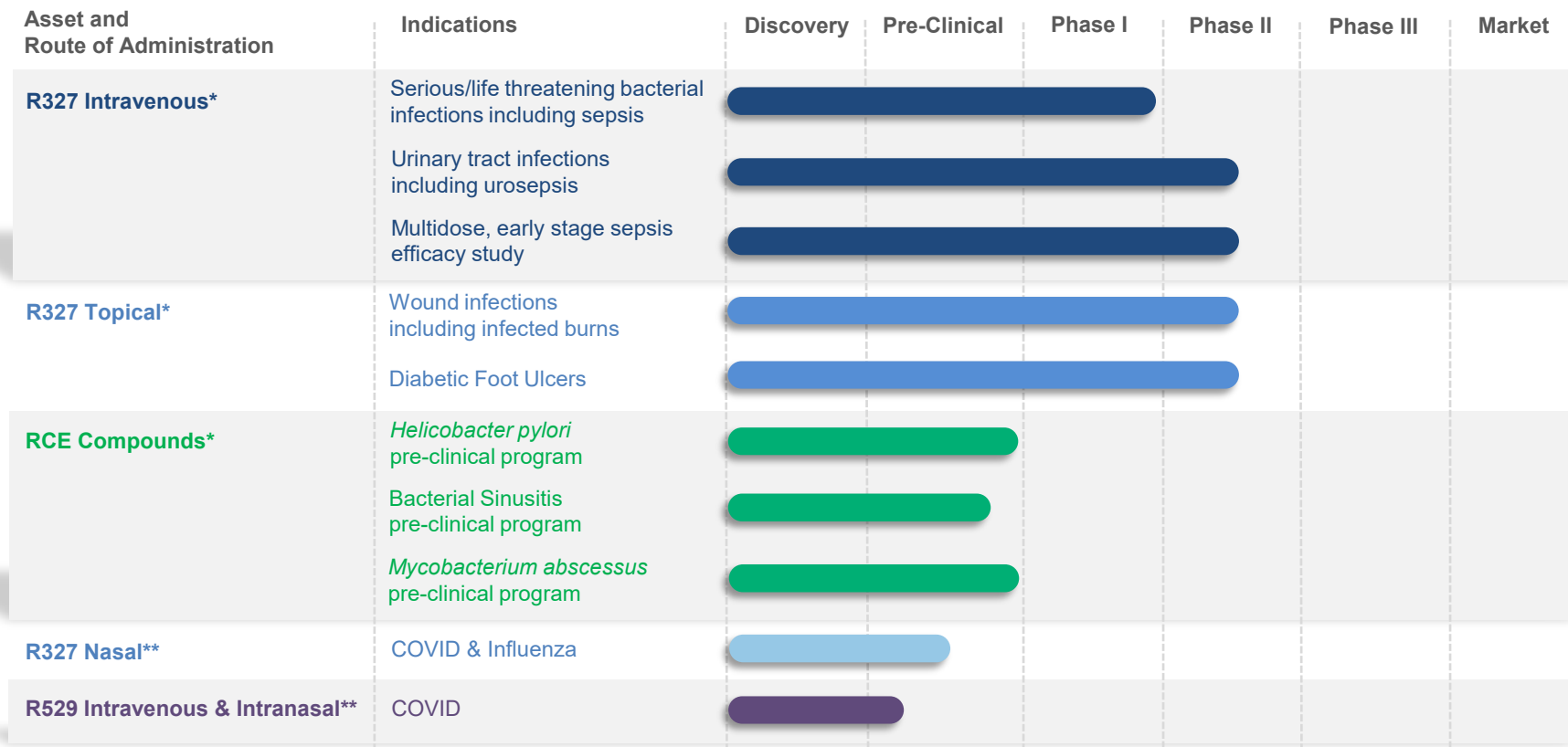
# A Versatile Technology Platform

- 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



# Strong Pipeline

## Over Various Indications and Upcoming Inflection Points



\*Anti-bacterial program

\*\*Anti-viral program

# Sepsis – it's a big problem!

48.9 million incident  
cases of **sepsis**  
recorded worldwide<sup>1</sup>



11 million sepsis-  
related **deaths** recorded<sup>2</sup>



**One in three** patients  
who **die** in hospital  
have sepsis<sup>3</sup>



- 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<sup>4</sup>.
- Is the **most expensive condition to treat** in the last 8 years<sup>5</sup>.
  - **Double the average cost per stay across all other conditions**<sup>5</sup>.
- Currently no drug therapies specifically for the treatment of sepsis<sup>6</sup>.



# 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).

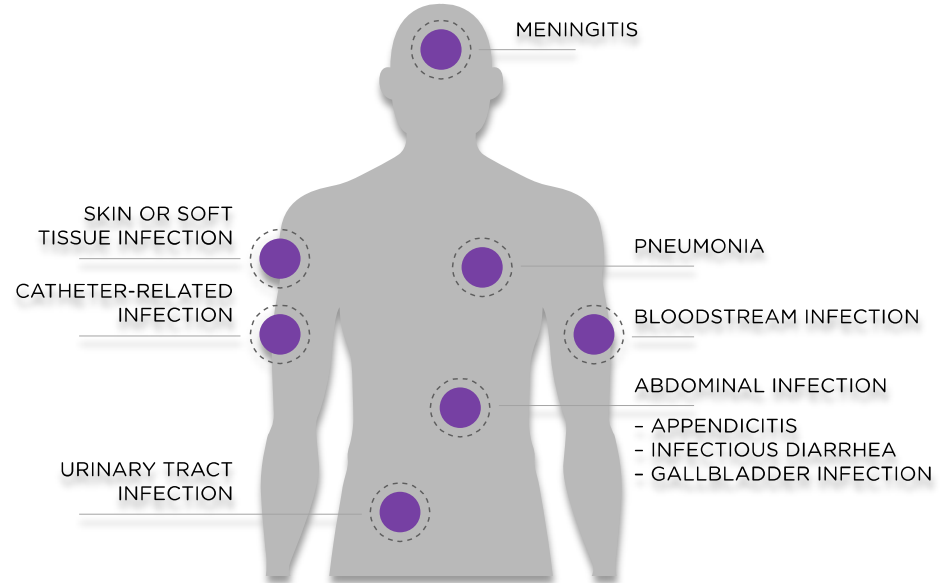


## Current Treatment Paradigm

- 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



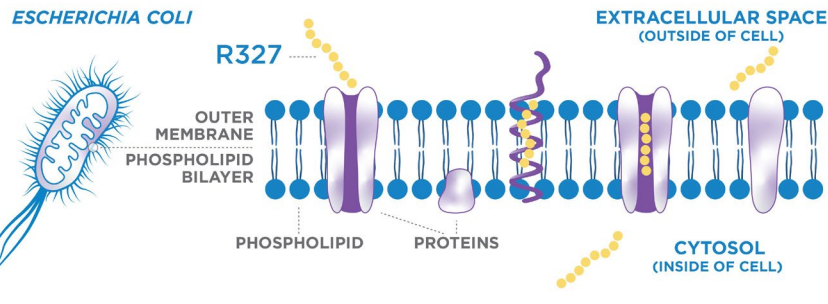
- **NO** pre-formed natural superbugs.
- Entirely **man-made** and designed with purpose.
- **Universal Mechanism of Action** - does not succumb to resistance.
- **Broad Spectrum capability** and maintains its activity even with repeated use.
- **Empowers clinicians** to confidently and quickly administer 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 MoA<sup>1</sup>

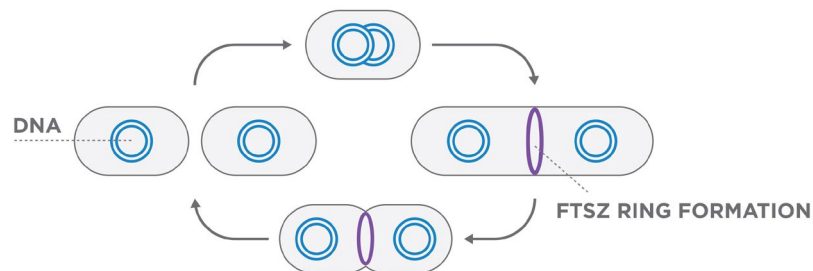
By Leading Experts in Bacterial MoA Analysis

## Stage 1



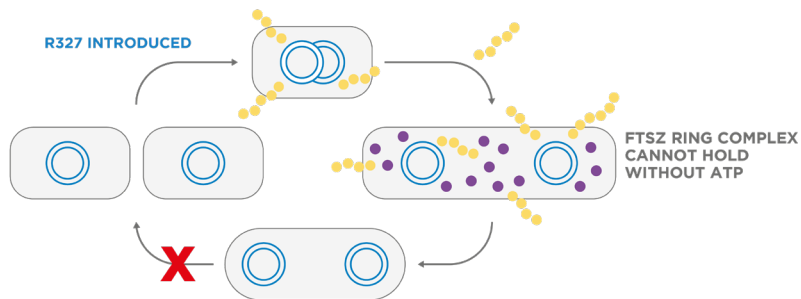
*R327 permeabilizes cell membrane and enters the cell*

## Stage 2



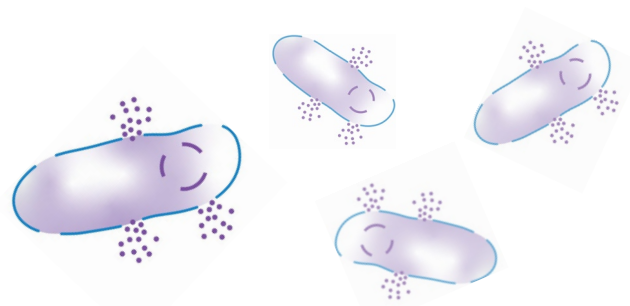
*R327 interrupts bacterial cellular energetics via ATP Synthesis*

## Stage 3



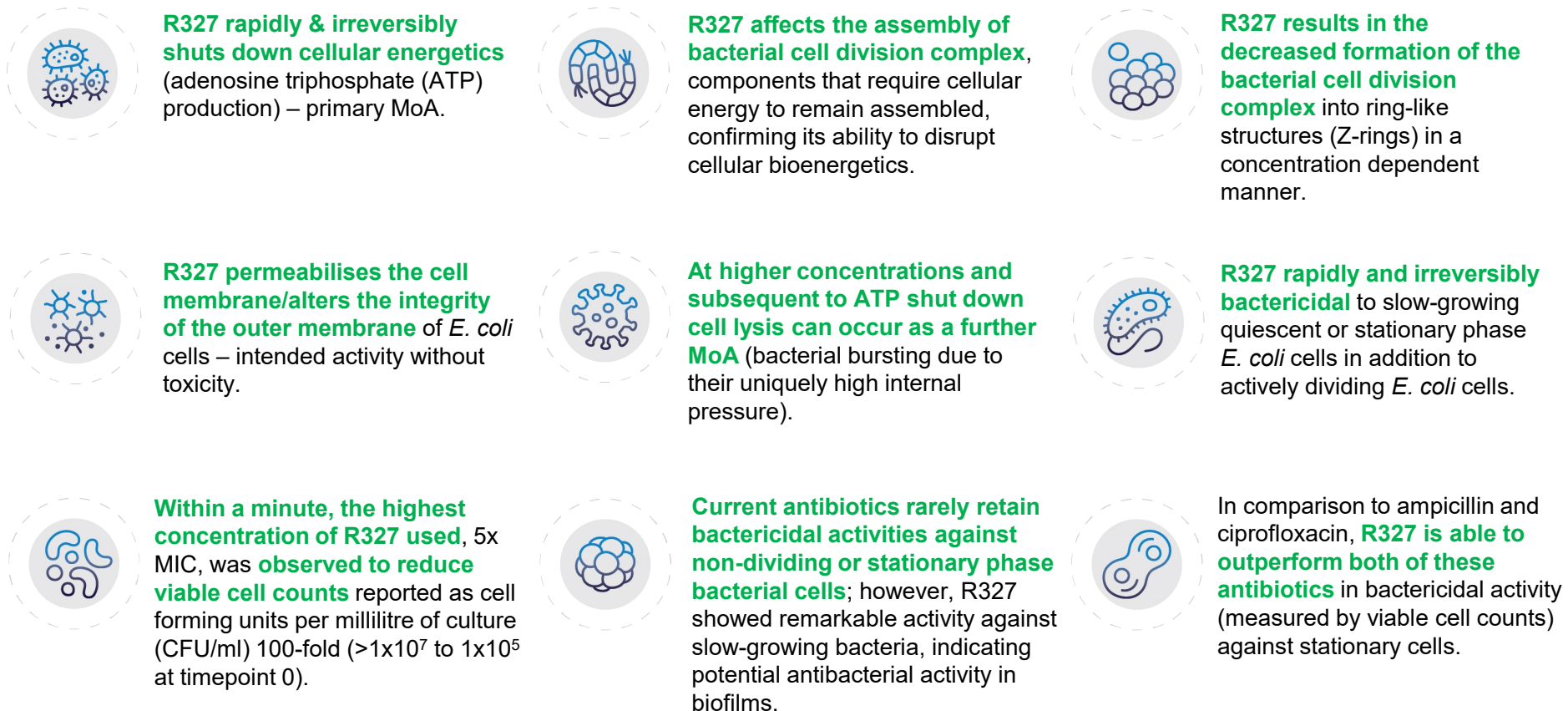
*Cellular division & non-dividing cell functions are disrupted*

## Stage 4



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

# RECCE® 327 Multi-Layered Mechanism of Action<sup>1</sup>



# 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***



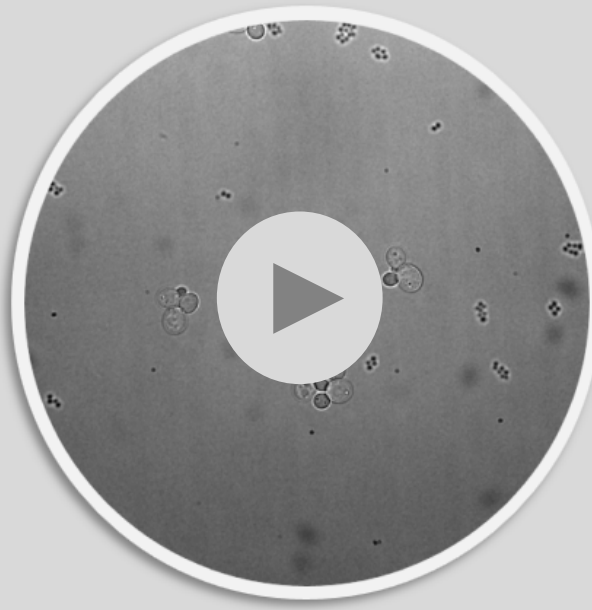
***R327 (3,000 ppm)***



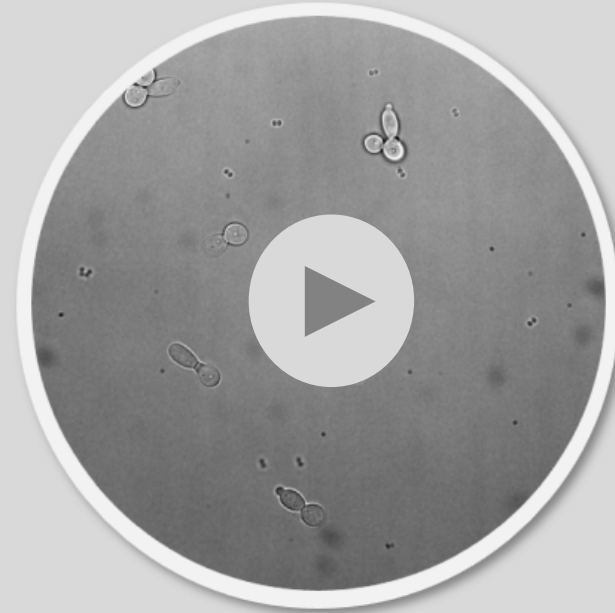
# RECCE® 327 Activity Against *Staphylococcus aureus*

- *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.

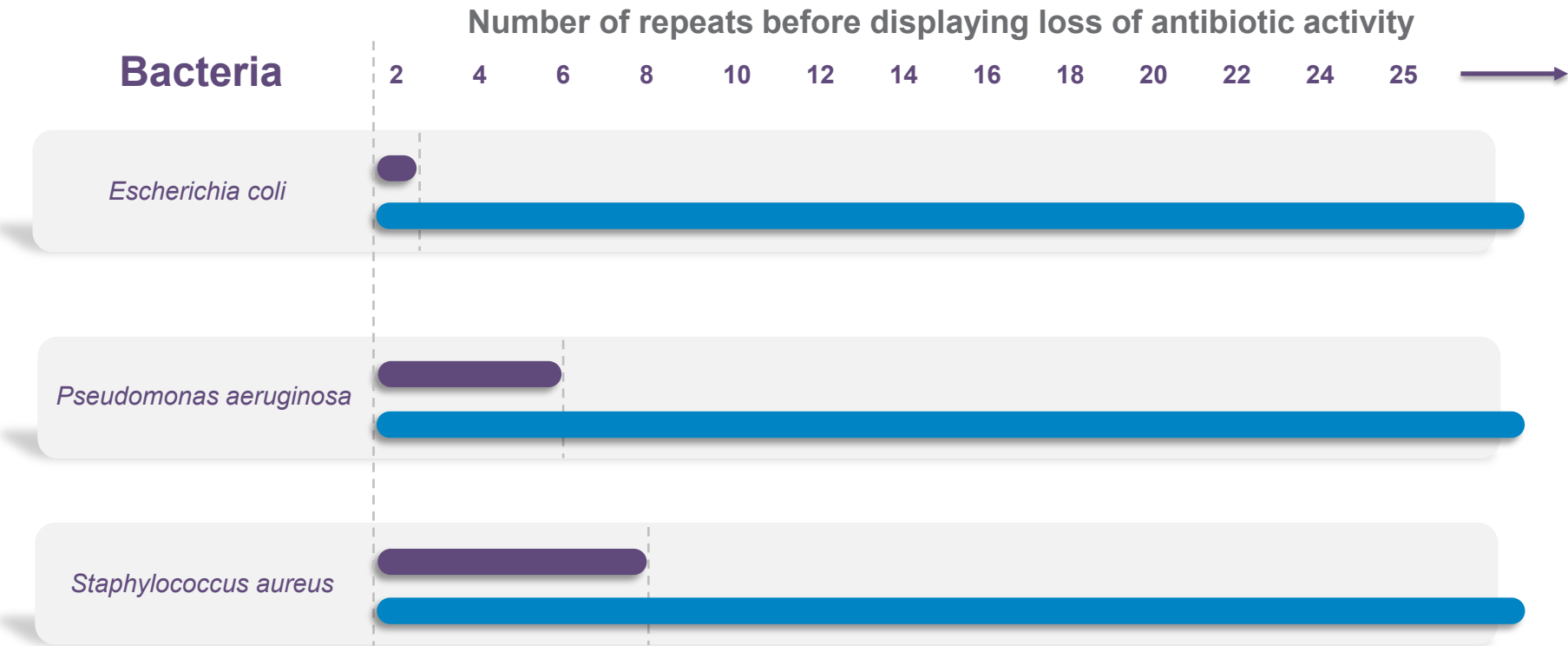
*Without R327*



*R327 (2,300 ppm)*



# RECCE<sup>®</sup> 327 Maintains Activity<sup>1</sup>



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

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

# Phase I Human Clinical Trial

- Study to assess IV infusion of RECCE® 327 in 80 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.



\*Dose increase fold based off 50mg



# Phase I Human Clinical Trial – ‘High Dose’

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

- Study objectives **broadly achieved** – now ‘dose-ceiling’ focused.
- 6,000mg (6 grams) over 1 hour IV is HIGH.
- **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.
- Next Phase preparations **well underway**

**High Dose**  
7-10 subjects in each  
cohort: 2 control, 8 R327

**120x** dose amount\*

**6,000 mg ✓**  
(& beyond?)

**80x** dose amount\*

**4,000 mg ✓**

**40x** dose amount\*

**2,000 mg ✓**





# Phase I Clinical Single-dose safety and PK study

## Reason for Optimism in Treating UTI/Sepsis

- **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.

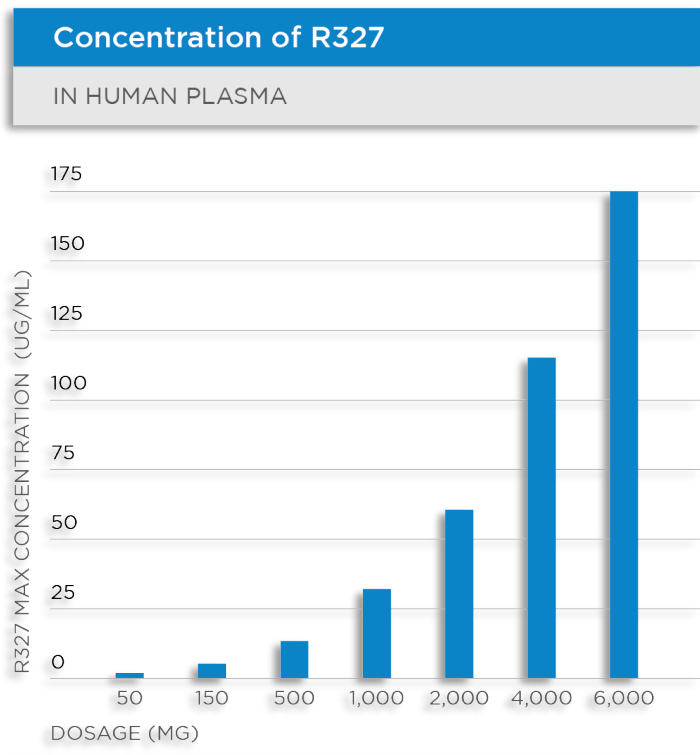
### In over 60 healthy subjects

Concentration of R327 in Urine Compared to Plasma

Dose (mg)	Concentration of R327 in Human Plasma – R327 Max Concentration (ug/ml)	Concentration of R327 in Human Urine – R327 Max Concentration (ug/ml)	Ratio Urine/Plasma -
50	1.4	21.3	15x
150	5.1	68.5	13x
500	13.5	204.5	15x
1,000	32	529.5	17x
2,000	60.5	860.7	14x
4,000	115	2352.2	20x
6,000	175	2295.7	13x



# Phase I Single-dose clinical study – R327 in Human Plasma

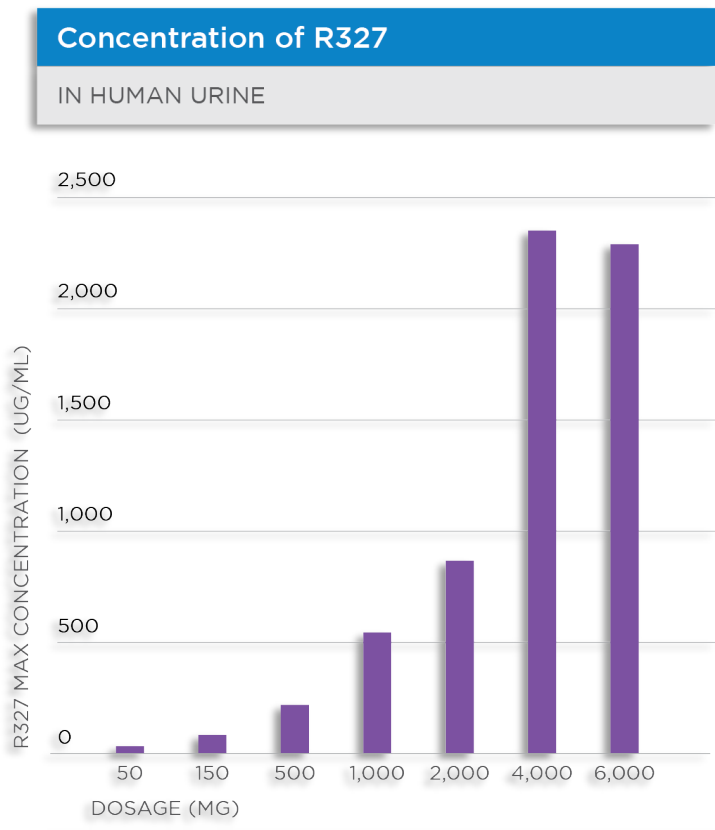


- Significant dose dependant concentration of R327 in subjects plasma (blood)
- R327 in human plasma – potential for interreaction with bacteria in the blood
- Compelling profile for a sepsis drug candidate

Dose (mg)	Concentration of R327 in Human Plasma – R327 Max Concentration (ug/ml)
50	1.4
150	5.1
500	13.5
1,000	32
2,000	60.5
4,000	115
6,000	175



# Phase I Single-dose clinical study – R327 in the Urinary Tract



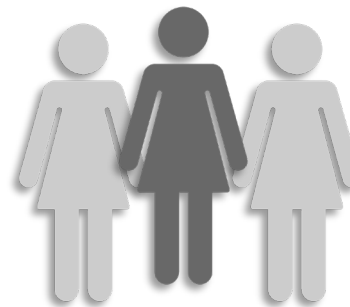
- Significant dose dependant concentration of R327 in subjects urine
- Compound concentrated in the urinary tract – potential for site specific interreaction with bacteria
- Compelling profile for a UTI drug candidate

Dose (mg)	Concentration of R327 in Human Urine - R327 Max Concentration (ug/ml)
50	21.3
150	68.5
500	204.5
1,000	529.5
2,000	860.7
4,000	2352.2
6,000	2295.7

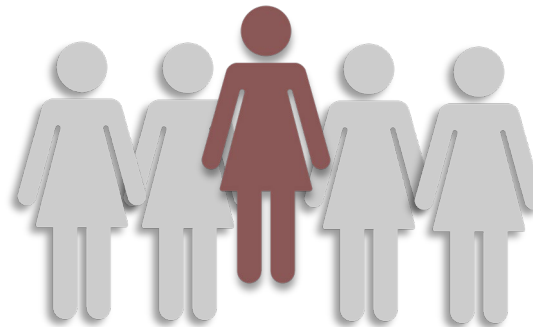


# Market Update – Background on UTIs

- **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



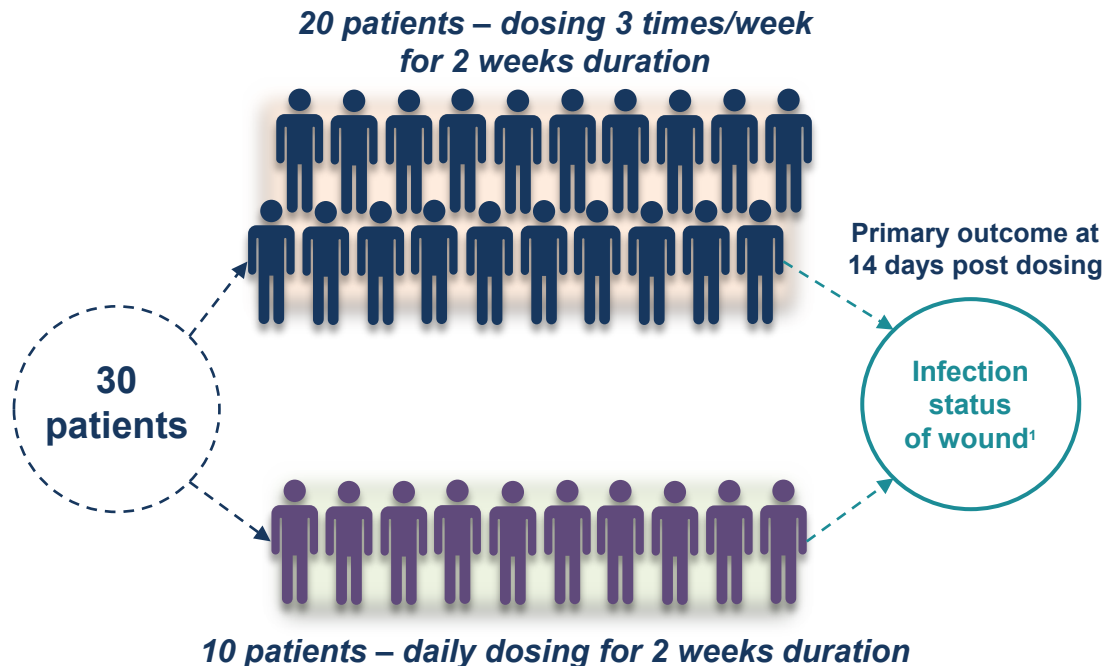
One in five are resistant to five other common antibiotics.



# Topical RECCE® 327 - Phase I/II

## Burn wound infections

- **Phase I/II** to assess Topical RECCE® 327 in burn wound infections commenced in Q4 2021.
- 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).



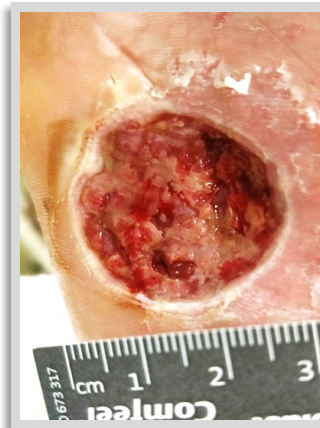
# Topical RECCE® 327 – Phase I/II

## Patient examples from ongoing Burn Wound trial

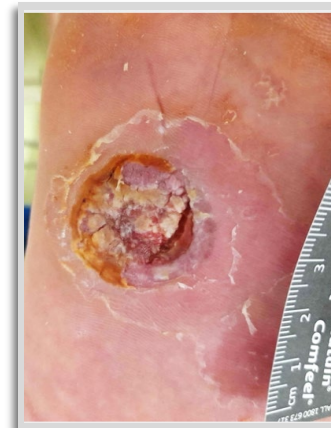
- Patients suffered major burn injury.
- Multiple bacterial species in and surrounding wound.
- Growth swabs with organisms including pathogens from the ESKAPE group of bacteria.
- Post R327 treatment: **healthy skin growth return, reduced swelling and infection, indications of tissue penetration to underlying infection.**

*Study data now under-review for next-step considerations.*

- 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.



*Pre-treatment, significant  
bacterial infection*



*Post R327 treatment*



# Patents

## Four families across all major markets

Country	Title	Case_Status	Grant_Date	Applicant	Family
Australia	ANTI-MICROBIAL POLYMERS AND THEIR COMPOSITIONS	Granted	25/08/2015	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
United Kingdom	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 Limited	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
United Kingdom	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	Report Received		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
Australia	PROCESS FOR PREPARATION OF BIOLOGICALLY ACTIVE COPOLYMER	Exam Requested		Recce Pharmaceuticals Ltd	Family 4
Brazil	PROCESS FOR PREPARATION OF BIOLOGICALLY ACTIVE COPOLYMER	Filed		Recce Pharmaceuticals Ltd	Family 4
Canada	PROCESS FOR PREPARATION OF BIOLOGICALLY ACTIVE COPOLYMER	Filed		Recce Pharmaceuticals Ltd	Family 4
China	PROCESS FOR PREPARATION OF BIOLOGICALLY ACTIVE COPOLYMER	Filing Sent		Recce Pharmaceuticals Ltd	Family 4
Europe	PROCESS FOR PREPARATION OF BIOLOGICALLY ACTIVE COPOLYMER	Filing Sent		Recce Pharmaceuticals Ltd	Family 4
Hong Kong	PROCESS FOR PREPARATION OF BIOLOGICALLY ACTIVE COPOLYMER	To be Filed		Recce Pharmaceuticals Ltd	Family 4
India	PROCESS FOR PREPARATION OF BIOLOGICALLY ACTIVE COPOLYMER	Filed		Recce Pharmaceuticals Ltd	Family 4
Japan	PROCESS FOR PREPARATION OF BIOLOGICALLY ACTIVE COPOLYMER	Filing Sent		Recce Pharmaceuticals Ltd	Family 4
PCT	PROCESS FOR PREPARATION OF BIOLOGICALLY ACTIVE COPOLYMER	PCT Filed		Recce Pharmaceuticals Ltd	Family 4
USA	PROCESS FOR PREPARATION OF BIOLOGICALLY ACTIVE COPOLYMER	Filed		Recce Pharmaceuticals Ltd	Family 4
Vietnam	PROCESS FOR PREPARATION OF BIOLOGICALLY ACTIVE COPOLYMER	Filing Sent		Recce Pharmaceuticals Ltd	Family 4
Israel	PROCESS FOR PREPARATION OF BIOLOGICALLY ACTIVE COPOLYMER COMPRISING AN ACROLEIN DERIVATIVE AND A POLYALKYLENE GLYCOL OLIGOMER	Direction Issued		Recce Pharmaceuticals Ltd	Family 4

*Recce's patent portfolio includes more than 40 patents and patent applications in the world's major markets.*



recce.com.au



# In-house 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 approx. 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 standards



[recce.com.au](http://recce.com.au)



# Recce Pharmaceuticals Ltd – Capital Structure

## Snapshot

Tickers ASX:RCE, FSE:R9Q

Market Cap (approx.) **AUD \$116 million**  
Priced at \$0.655

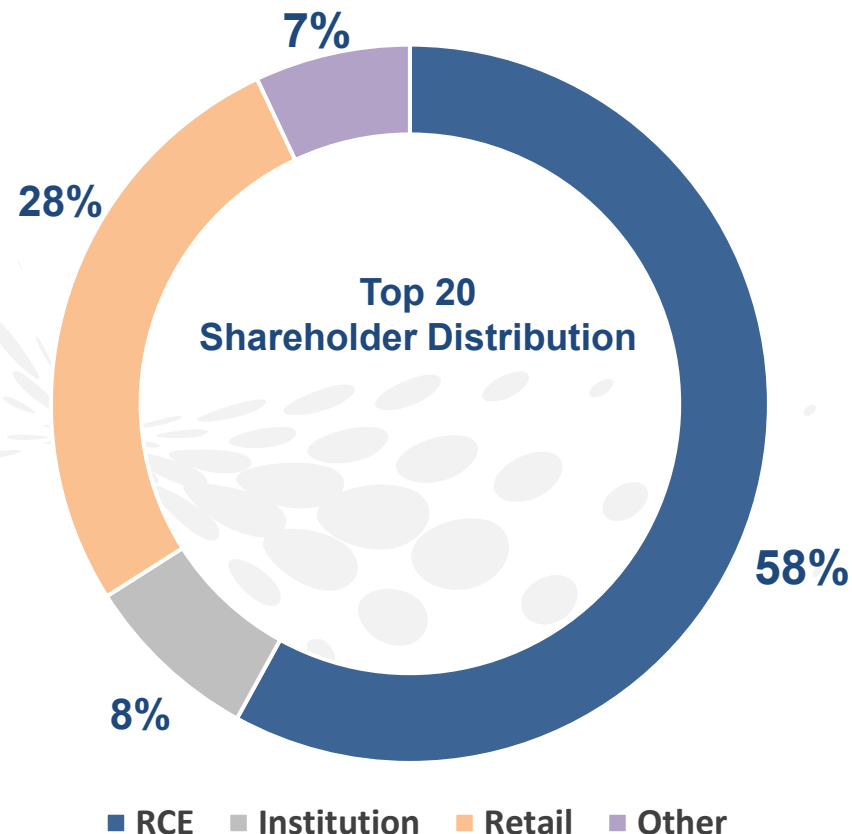
Cash and deposits\* **AUD \$5.73 million**  
1 October 2022

Outstanding shares **178.08 million**

Average daily volume **82.41k**  
3 months

Debt **Nil**

*\*Pre >\$3.5m R&D rebate + other non-dilutionary cash in-flows expected this quarter - actual cash runway circa AUD \$10 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 Q4 2022)
  - 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 Q4 2022)



# Investment Summary



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



Fast development plans initially targeting: **Sepsis, 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 and Phase II 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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