

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 **3rd November, Thursday at 5:45PM AEDT**

Please register using the link below:

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.



ASX: RCE, **FSE:** R9Q

Head Office: Level 25, 88 Phillip Street, Aurora Place, SYDNEY NSW 2000 **T** +61 (02) 9256 2571

R&D Centre - Perth: Suite 10, 3 Brodie Hall Drive, Technology Park, BENTLEY WA 6102 **T** +61 (8) 9362 9860

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

Corporate Presentation

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.



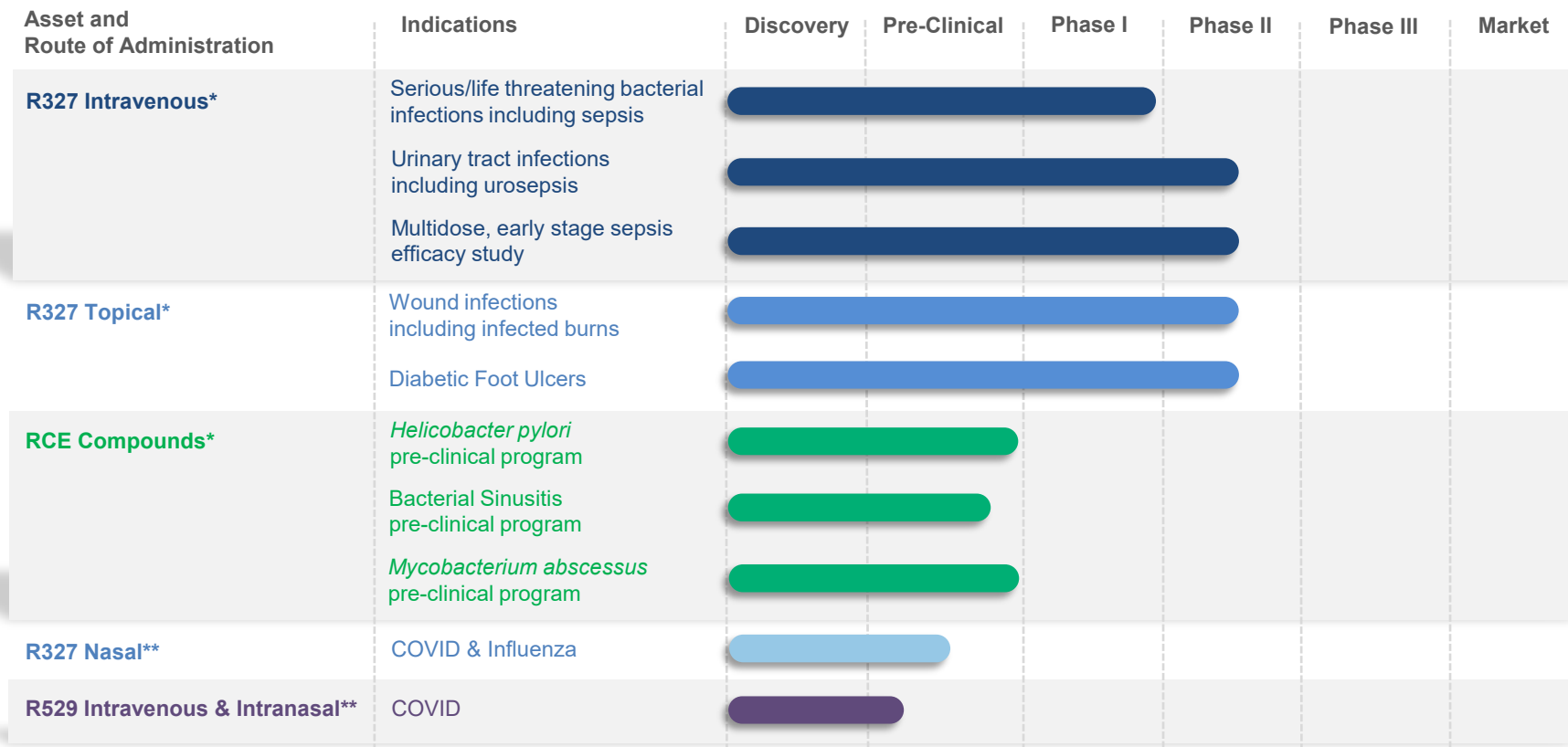
A Versatile Technology Platform

- 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!

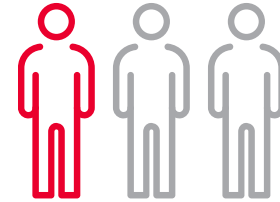
48.9 million incident
cases of **sepsis**
recorded worldwide¹



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).

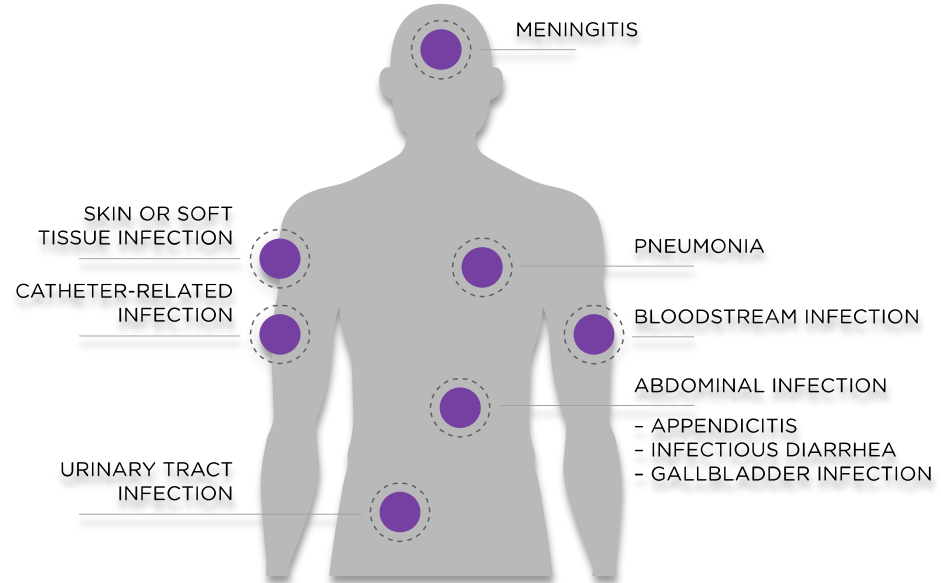


Current Treatment Paradigm

- 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



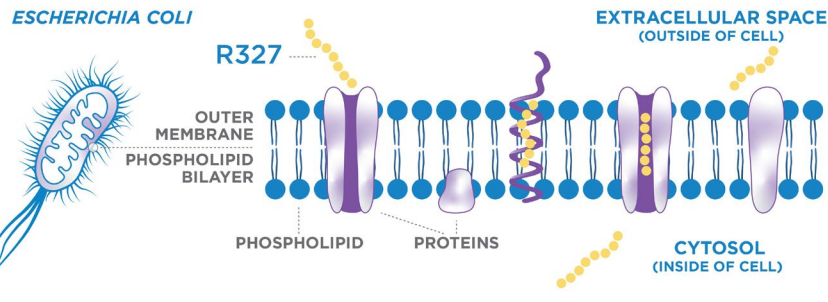
- **NO** pre-formed natural superbugs.
- Entirely **man-made** and designed with purpose.
- **Universal Mechanism of Action** - does not succumb to resistance.
- **Broad Spectrum capability** and maintains its activity even with repeated use.
- **Empowers clinicians** to confidently and quickly administer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

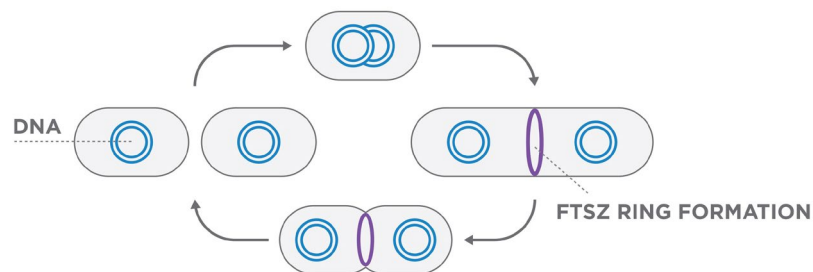
By Leading Experts in Bacterial MoA Analysis

Stage 1



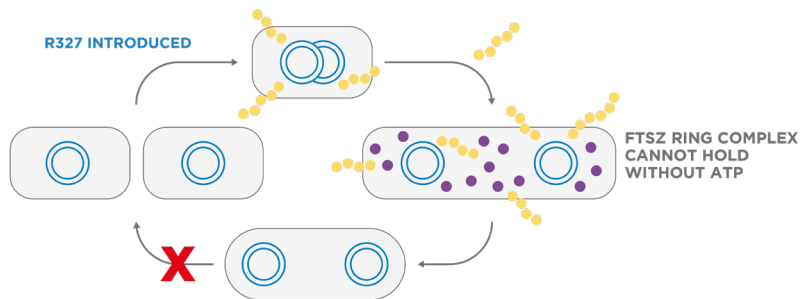
R327 permeabilizes cell membrane and enters the cell

Stage 2



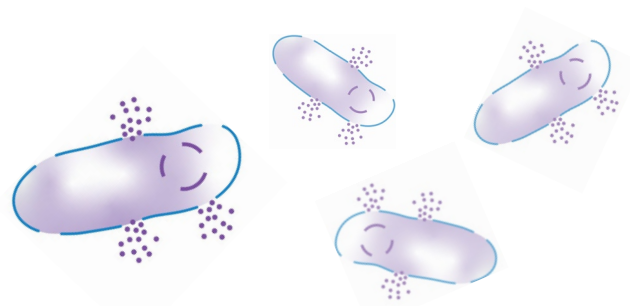
R327 interrupts bacterial cellular energetics via ATP Synthesis

Stage 3



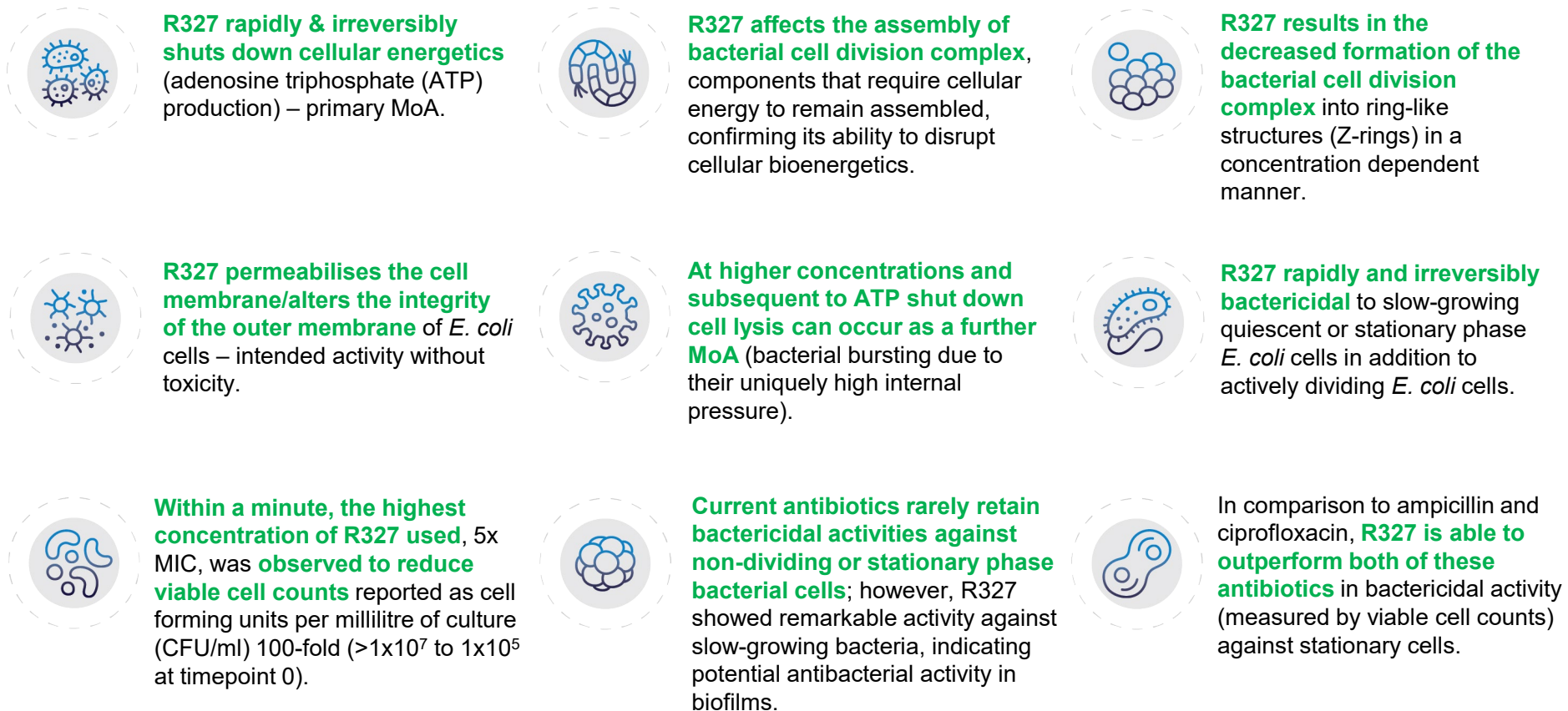
Cellular division & non-dividing cell functions are disrupted

Stage 4



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

RECCE[®] 327 Multi-Layered Mechanism of Action¹



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



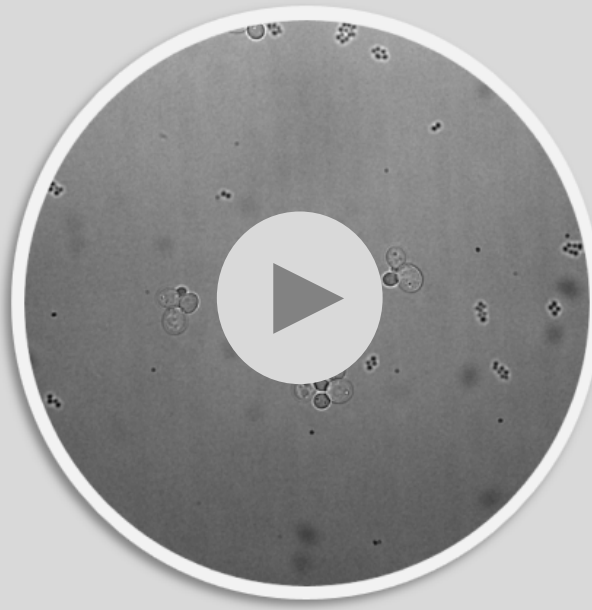
R327 (3,000 ppm)



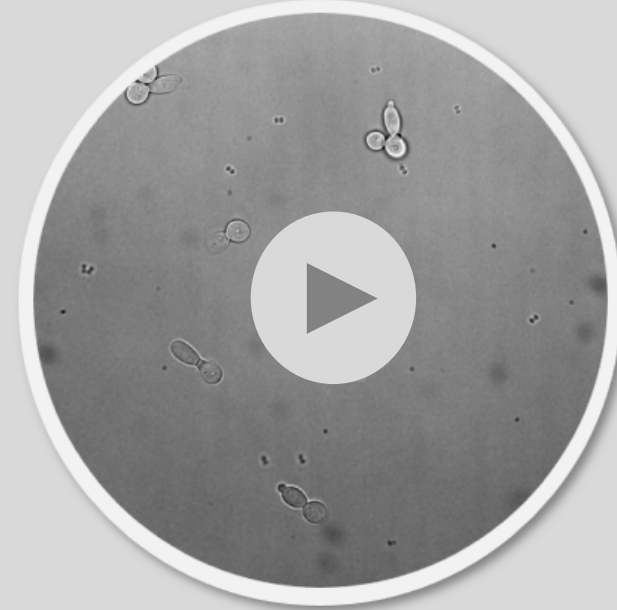
RECCE® 327 Activity Against *Staphylococcus aureus*

- *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.

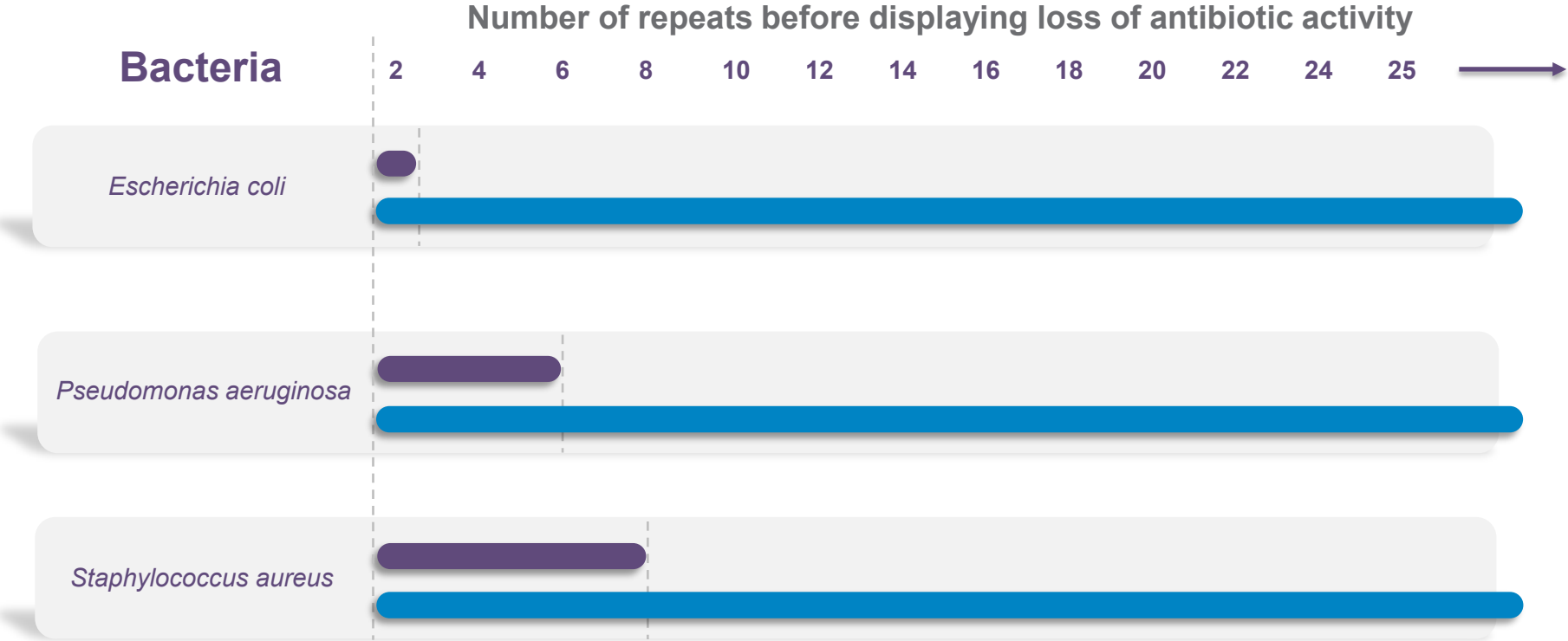
Without R327



R327 (2,300 ppm)



RECCE[®] 327 Maintains Activity¹



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

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.

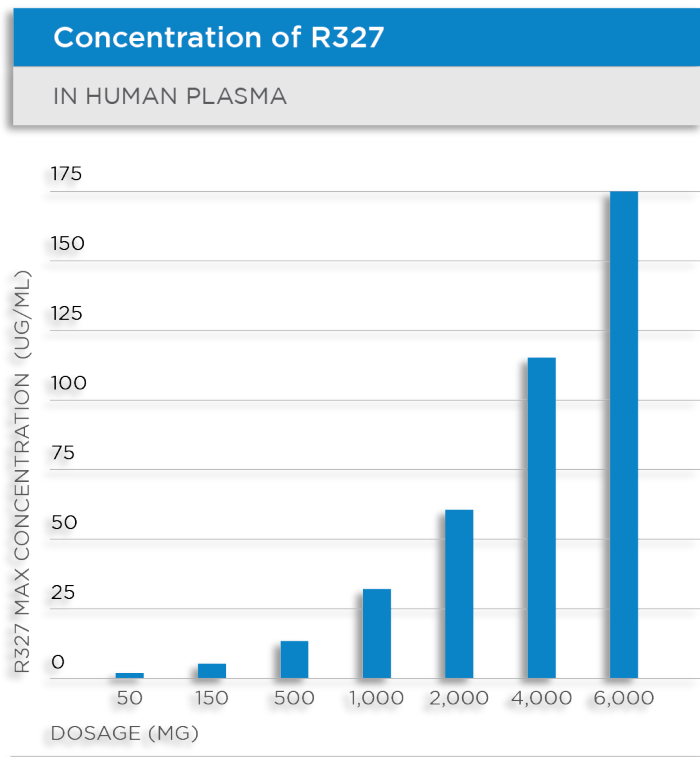
In over 60 healthy subjects

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

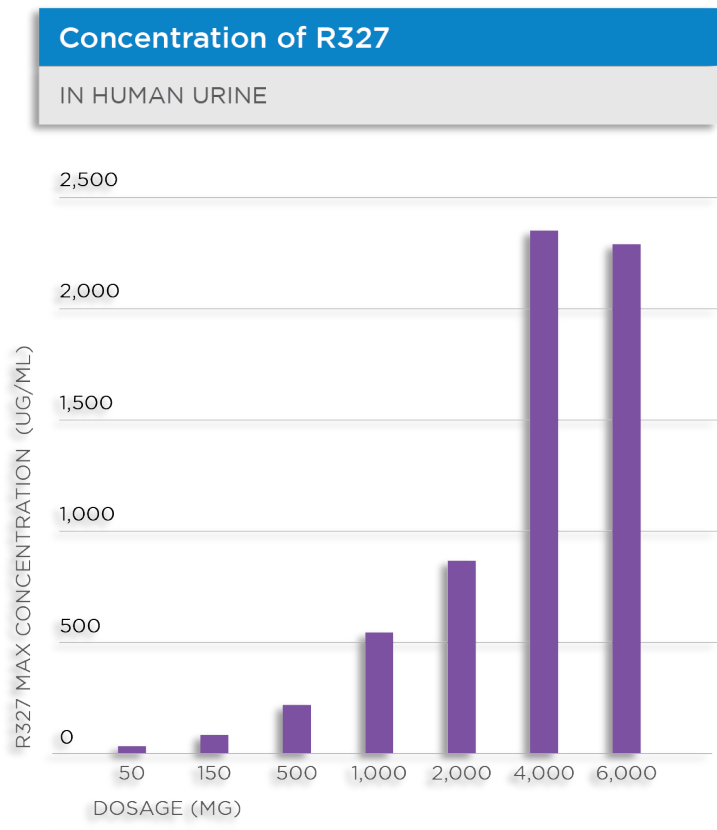


- Significant dose dependant concentration of R327 in subjects plasma (blood)
- R327 in human plasma – potential for interreaction with bacteria in the blood
- Compelling profile for a sepsis drug candidate

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



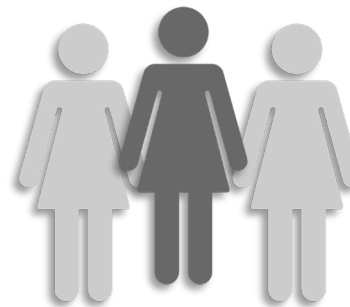
- Significant dose dependant concentration of R327 in subjects urine
- Compound concentrated in the urinary tract – potential for site specific interreaction with bacteria
- Compelling profile for a UTI drug candidate

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

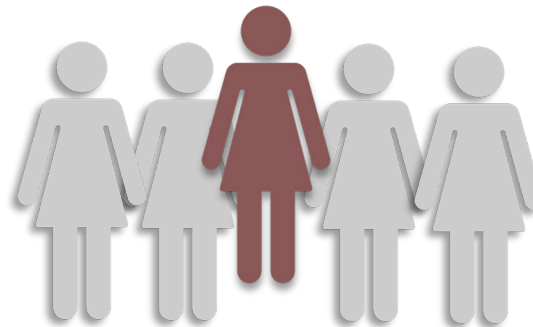


Market Update – Background on UTIs

- **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



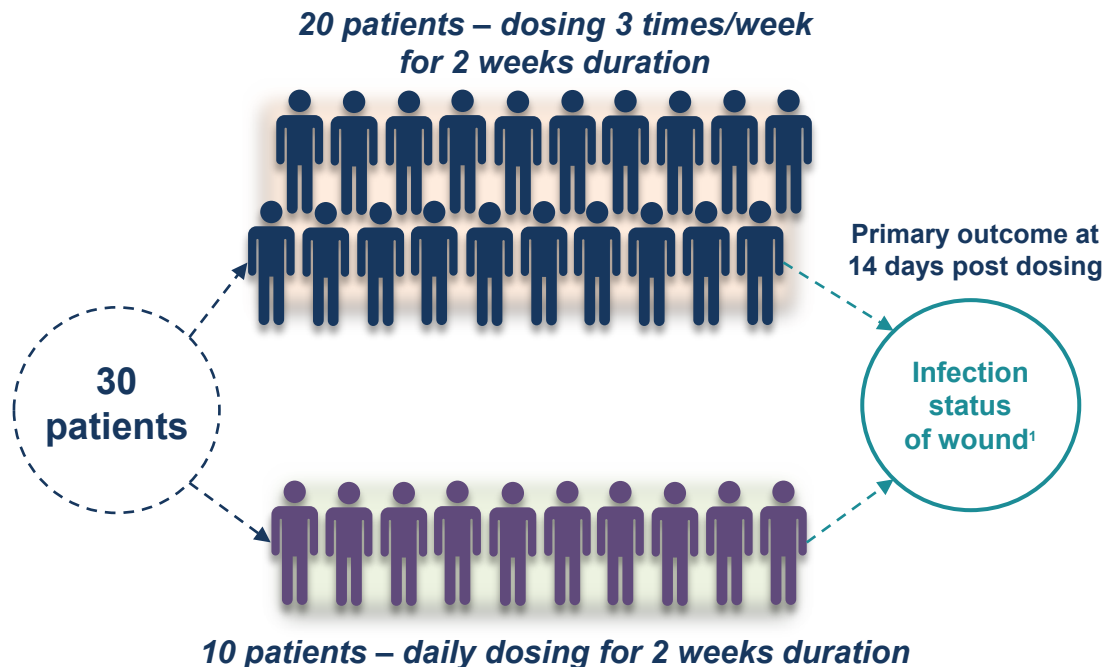
One in five are resistant to five other common antibiotics.



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

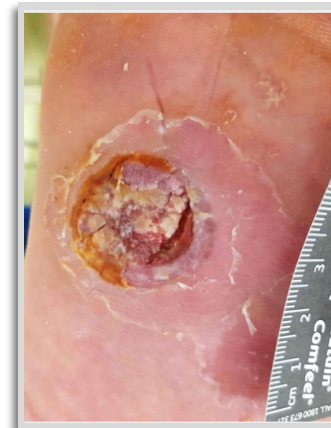
- Patients suffered major burn injury.
- Multiple bacterial species in and surrounding wound.
- Growth swabs with organisms including pathogens from the ESKAPE group of bacteria.
- Post R327 treatment: **healthy skin growth return, reduced swelling and infection, indications of tissue penetration to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

Recce Pharmaceuticals Ltd – Capital Structure

Snapshot

Tickers ASX:RCE, FSE:R9Q

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

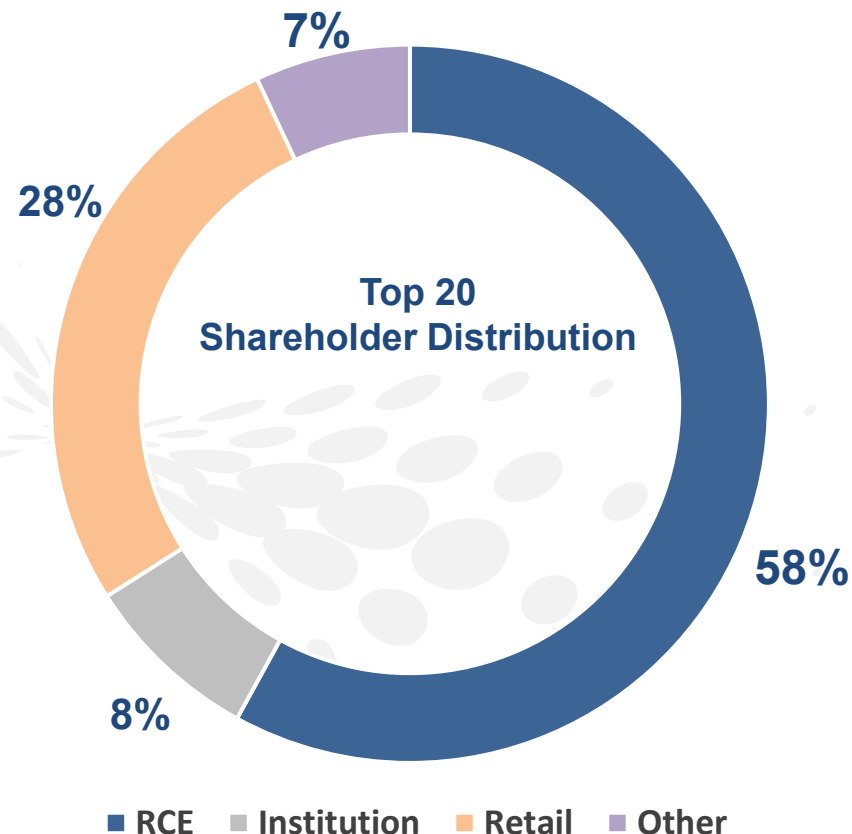
Cash and deposits* **AUD \$5.73 million**
1 October 2022

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

☎ +61 2 9256 2572

✉ james.graham@recce.com.au



recce.com.au