

ASX Announcement

Biotech Investors Luncheon – Emerging Biotech Conquering Global Markets

SYDNEY Australia, 16 May 2022: Recce Pharmaceuticals Ltd (**ASX:RCE, FSE:R9Q**) (the **Company**), the Company developing a New Class of Synthetic Anti-infectives, is pleased to announce its participation alongside Genetic Technologies (**ASX:GTG; NASDAQ:GENE**) and Medlab Clinical Ltd (**ASX:MDC**) in the “Biotech Investors’ Luncheon”, held at the Sofitel Wentworth in Sydney 12.30PM on Monday 16 May 2022.

The luncheon is proudly sponsored by Blue Ocean Equities and Davies Collison Cave Lawyers.

Please find provided below a copy of Recce Pharmaceuticals updated corporate presentation to be presented by Chief Executive Officer, James Graham.

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

For further information contact:



Simon Morriss
CEO Genetic Technologies Ltd
T: +61 408 579 593
Simon.morriss@gtqlabs.com



Dr. Sean Hall
CEO Medlab Clinical Ltd
T: +61 411 603 378
Sean_hall@medlab.co



James Graham
CEO Recce Pharmaceuticals
T: +61 431 978 682
James.graham@recce.com.au



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



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Biotech Investor Lunch



medlab



May 2022

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Management Structure



Dr John Prendergast – 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.



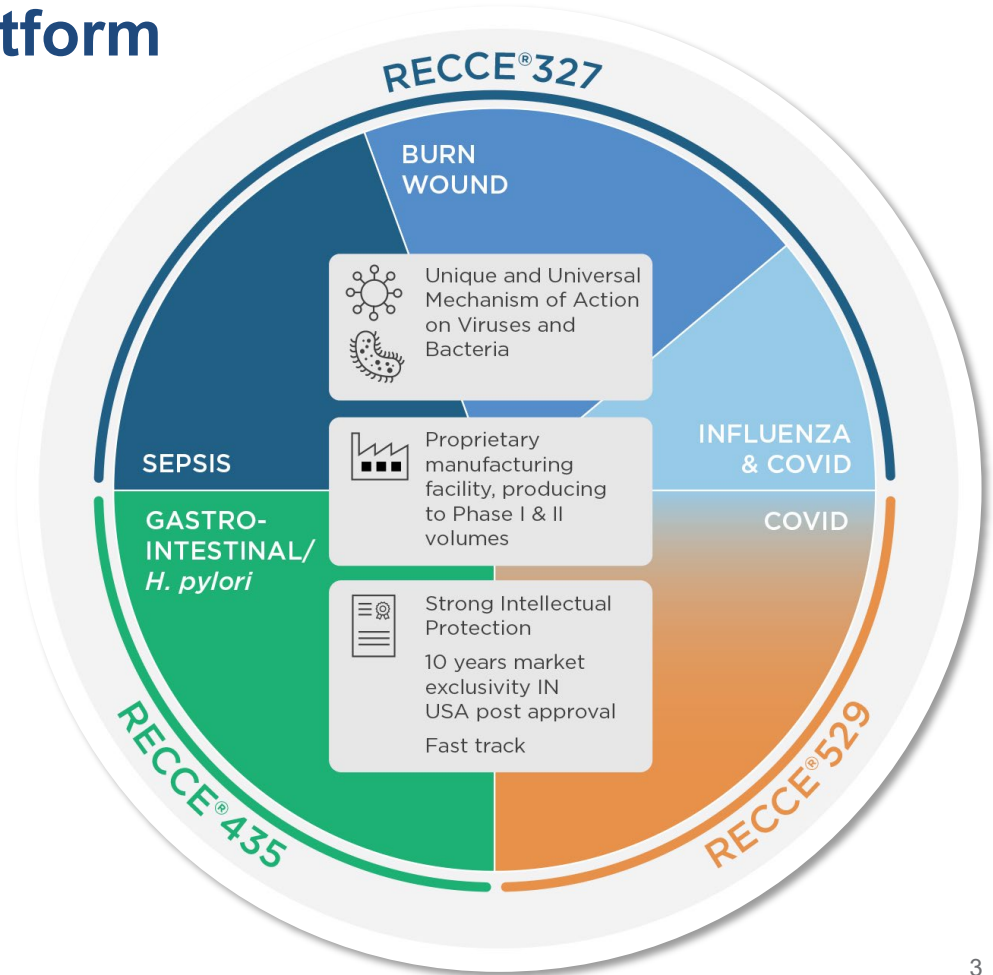
Michele Dilizia – Chief Scientific Officer

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
- ▶ **Versatile delivery platform** – oral, intravenous and spray formulations
- ▶ Designed to safely provide treatment **without developing resistance** over time
- ▶ Multiple opportunities with RECCE® 327 further **human data** expected in Q2 2022






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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	Serious/life threatening bacterial infections including sepsis						Further interim data readout Q2 2022	47-50 million cases worldwide.
R327 Topical	Wound infections including infected burns						Further interim data Q2 2022	11 million burn wound cases requiring medical intervention. Majority of which escalate to infection.
R435 Oral R529	<i>Helicobacter pylori</i> in stomach ulcers							4.4 billion people infected worldwide.

Anti-viral programs

R327 Nasal	COVID & Influenza							
R529 IV and Intranasal	COVID							

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

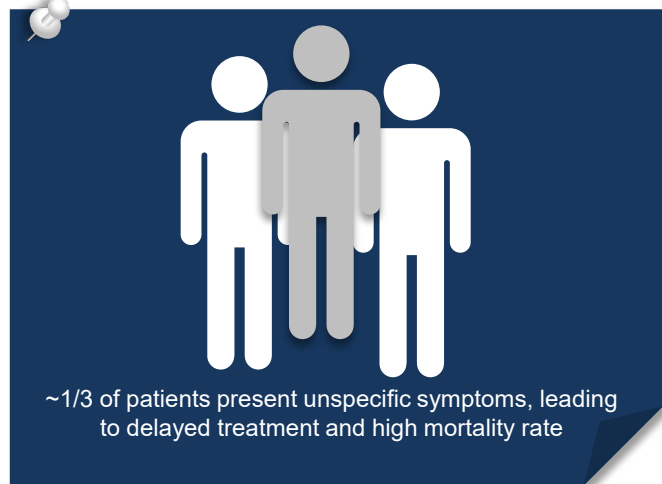


- ▶ Sepsis is a life-threatening inflammatory response to infection that has spread in the body.
 - ▶ Kills more people in the US than **prostate, breast cancer** and **HIV/AIDS** combined⁴.
- ▶ Is the **most expensive condition to treat** in the last 8 years⁵.
 - ▶ **Double the average cost per stay across all other conditions**⁵.
- ▶ Currently no drug therapies specifically for the treatment of sepsis⁶.

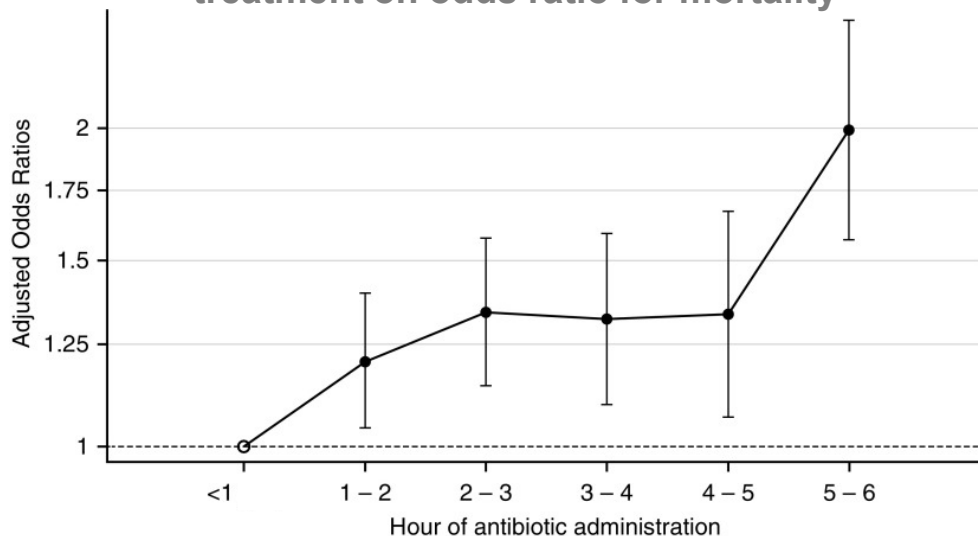


Sepsis Treatment Paradigm

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



Impact of delayed antibiotic treatment on odds ratio for mortality¹



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

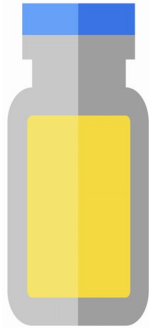
Mortality from sepsis increases by as much as 8% for every hour that treatment is delayed²

Natural Antibiotics vs Synthetic Anti-Infectives



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 Anti-Infective

- ▶ **NO** pre-formed natural superbugs.
- ▶ Entirely man-made and designed with purpose.
- ▶ Universal Mechanism of Action - detailed experimentation demonstrates it does not succumb to superbugs.
- ▶ Contains only what we want - not reliant on what’s found in nature.
- ▶ Broad-spectrum capability and maintains its activity even with repeated use!

Independent Study Undertaken on R327 MoA¹

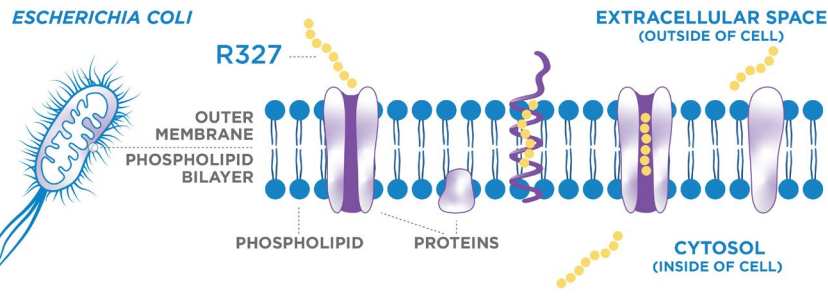
By Leading Experts in Bacterial MoA Analysis

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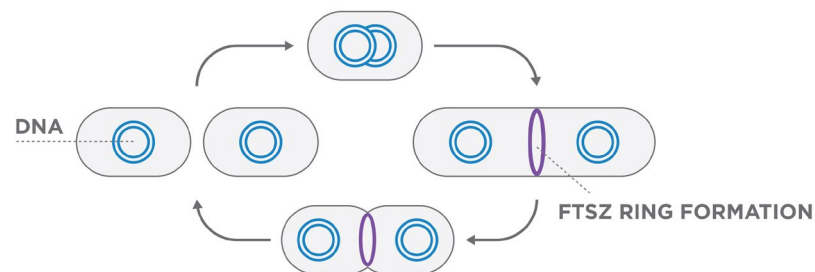
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Stage 1



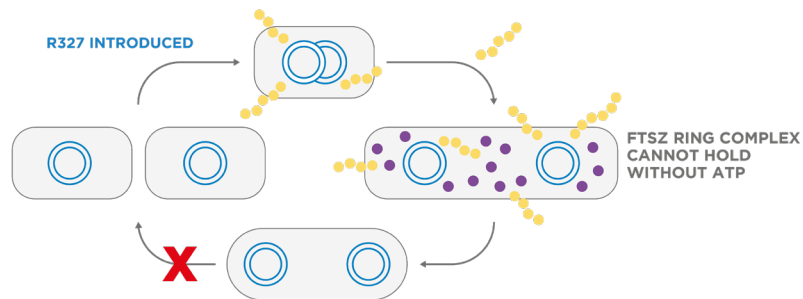
R327 permeabilizes cell membrane and enters the cell

Stage 2



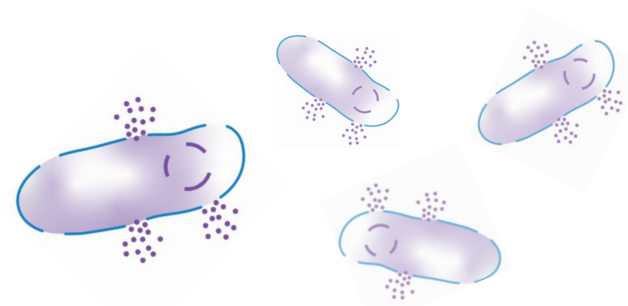
R327 interrupts bacterial cellular energetics via ATP Synthesis

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



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).



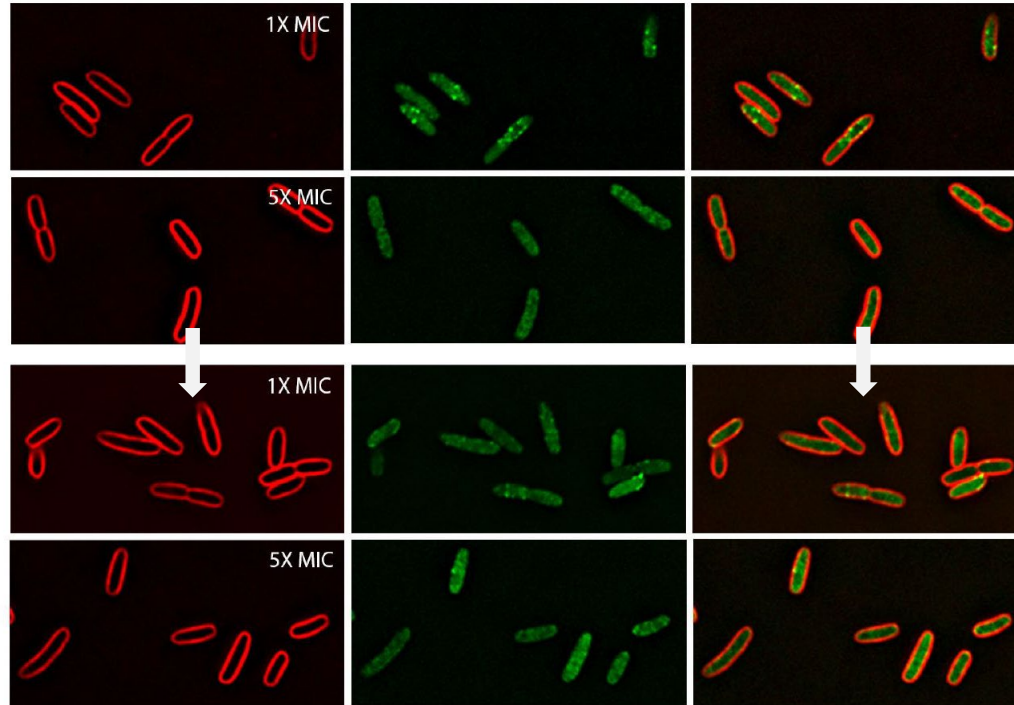
Current antibiotics rarely retain bactericidal activities against non-dividing or stationary phase bacterial cells; however, R327 showed remarkable activity against slow-growing bacteria, indicating potential antibacterial activity in biofilms.



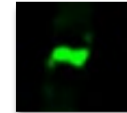
In comparison to ampicillin and ciprofloxacin, **R327 is able to outperform both of these antibiotics** in bactericidal activity (measured by viable cell counts) against stationary cells.

RECCE® 327 Mechanism of Action in Practice

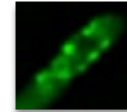
Treatment of R327 against E. coli at 1x and 5x MIC leading to disassembly of the FtsZ-GFP rings, supporting initial studies which indicated R327 inactivates cellular bioenergetics and is rapidly and irreversibly bactericidal.



Key:



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



Disassembled 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.



recce.com.au

Phase I Human Clinical Trial

Further Safety and Tolerability Interim Data Expected Q2 2022

- Study to assess IV infusion of RECCE® 327 in 80 healthy male subjects as a single ascending dose
- First cohort 9 subjects dosed December 2021
- Second cohort 7 subjects dosed January 2022
- Third cohort 10 subjects dosed February 2022
- Fourth cohort 10 subjects dosed March 2022
- 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.

Further interim data expected Q2 2022
Full data expected early H1 2022

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

320x dose amount*	16,000 mg
160x dose amount*	8,000 mg
80x dose amount*	4,000 mg
40x dose amount*	2,000 mg

Low Dose
36 subjects successfully
dosed across Cohorts 1-4

20x dose amount*	1,000 mg ✓
10x dose amount*	500 mg ✓
3x dose amount*	150 mg ✓
1x dose amount	50 mg ✓

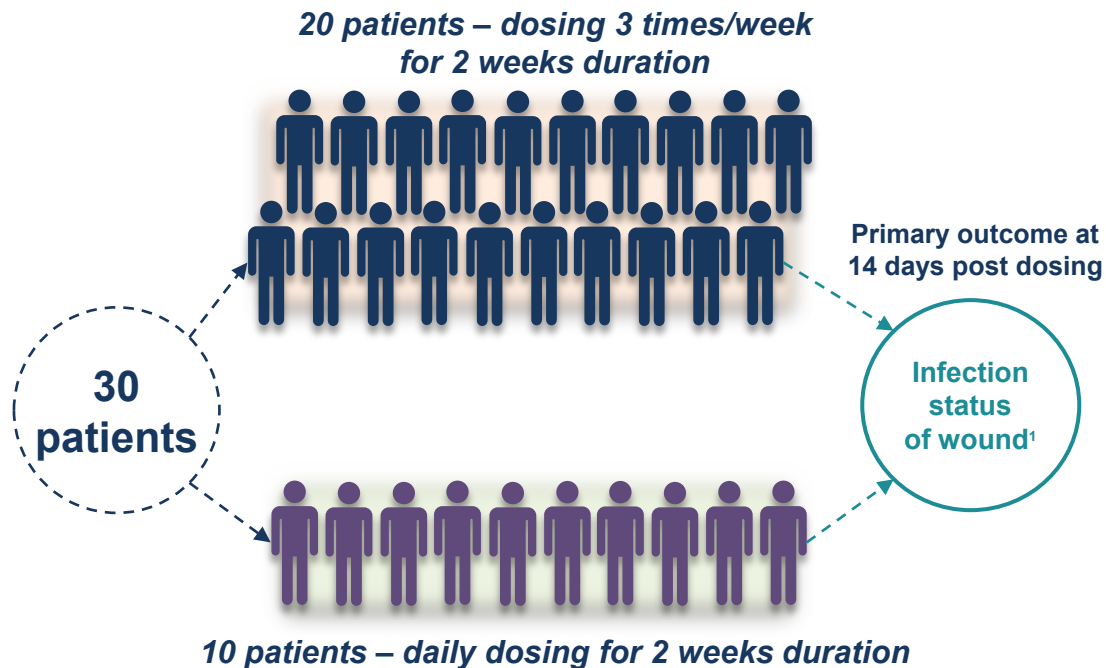
*Dose increase fold based off 50mg



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 example from ongoing Burn Wound trial

- ▶ Patient 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, infection cleared, indications of tissue penetration to underlying infection.**
- ▶ **No significant adverse effects or abnormalities.**
- ▶ Recruitment ongoing, patients treated with R327 demonstrating similar responses.



Pre-treatment, significant bacterial infection



Post R327 treatment



Patents

Three families across all major markets

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

- ▶ Family 1 group relates to the Company's unique and highly economical manufacturing process and use of the polymer in treatment of diseases.

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

- ▶ Family 2 relates to the method of manufacture, administration and application to treat a broad range of common human infections.

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

- ▶ Family 3 relates to a method of treatment of a broad range of viral infections, particularly parenteral viral infection.



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



Recce Pharmaceuticals Ltd – Capital Structure

Snapshot

Tickers ASX:RCE, FSE:R9Q

Amount Raised to Date AUD \$46 million

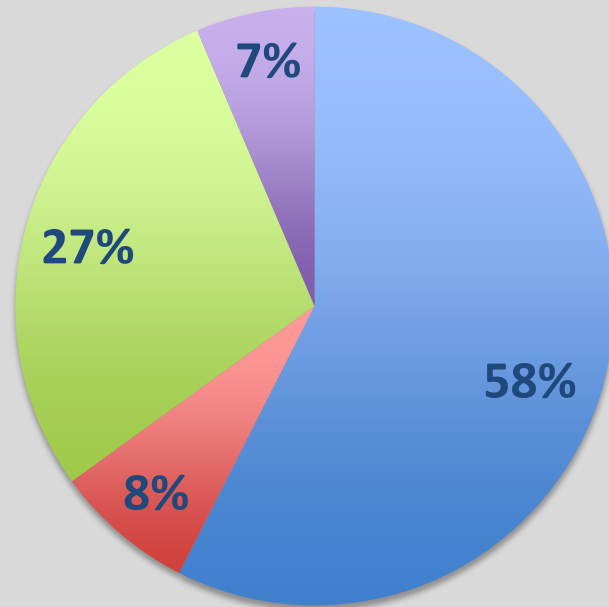
Market Cap (approx.)
13 May 2022 AUD \$137 million

Cash and deposits
3 April 2022 AUD \$15.90 million

Outstanding shares 174.54 million

Average daily volume
3 months 130.92k

Top 20 Shareholders Distribution



■ RCE ■ Institution ■ Retail ■ Other



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, Helicobacter pylori** and **COVID-19**.



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**.



R327 Phase I clinical trial – Subjects in Cohorts 1-4 dosed delivering further interim data Q2 2022.
Topical Phase I/II human clinical study of R327 commenced Q4 2021; further interim data expected Q2 2022.



Robust financial position to deliver clinical data.



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



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