Recce Pharmaceuticals

ASX:RCE FSE:R9Q

Corporate Presentation

Aussie Equities Day 2022

Spark+

July 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
- 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

**Awarded by the US FDA in 2017 for R327 bacteraemia (broad-spectrum bacterial sepsis). Time starts only from potential market approval.*

Strong Pipeline

Over Various Indications and Upcoming Inflection Points

Asset Route of administration	Indications	Discovery	Preclinical	Phase I	Phase II	Phase III	Market Size
Anti-bacterial programs							
R327 **Intravenous**	Serious/life threatening bacterial infections including sepsis						47-50 million cases worldwide.
R327 **Topical**	Wound infections including infected burns						11 million burn wound cases requiring medical intervention. Majority of which escalate to infection.
RCE **Compounds**	Multiple ongoing pre-clinical programs						-
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 worldwide[1]

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

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

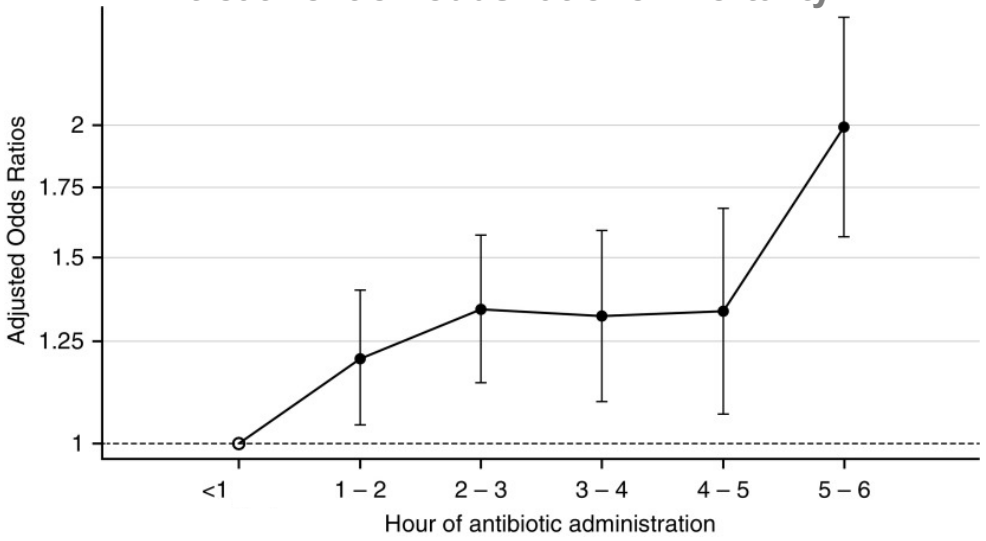
- Sepsis is a life-threatening inflammatory response to infection that has spread in the body.
  - Kills more people in the US than **prostate**, **breast cancer** and **HIV/AIDS** combined[4].
- Is the **most expensive condition to treat** in the last 8 years[5].
  - **Double the average cost per stay 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

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 mortality[1]



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 delayed[2]

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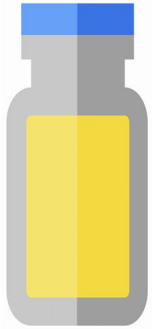
1 – Vincent X. Liu et al. The Timing of Early Antibiotics and Hospital Mortality in Sepsis - Am J Respir Crit Care Med. 2017 Oct 1; 196(7): 856–863.
2 – https://www.sepsis.org/wp-content/uploads/2017/05/Sepsis-Fact-Sheet-2018.pdf

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!

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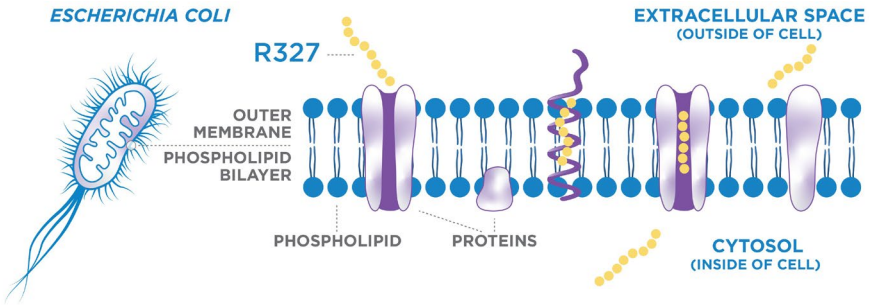
1- Lee, C E et al. "The incidence of antimicrobial allergies in hospitalized patients: implications regarding prescribing patterns and emerging bacterial resistance." Archives of internal medicine vol. 160,18 (2000): 2819-22. doi:10.1001/archinte.160.18.2819

Independent Study Undertaken on R327 MoA[1]

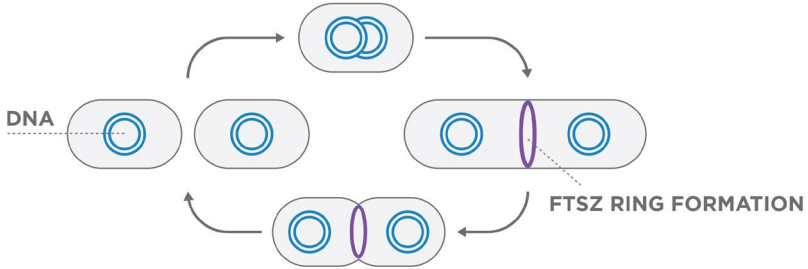
By Leading Experts in Bacterial MoA Analysis

Stage 1



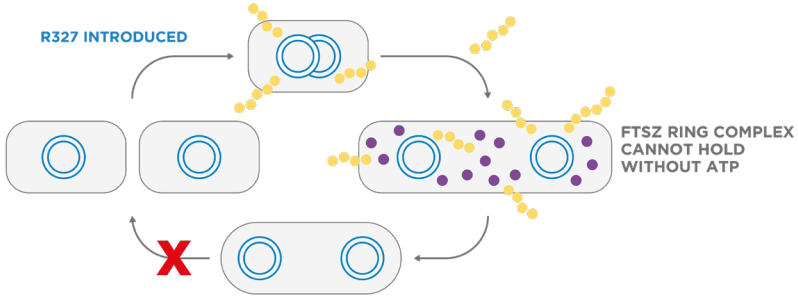
R327 permeabilizes cell membrane and enters the cell

Stage 2



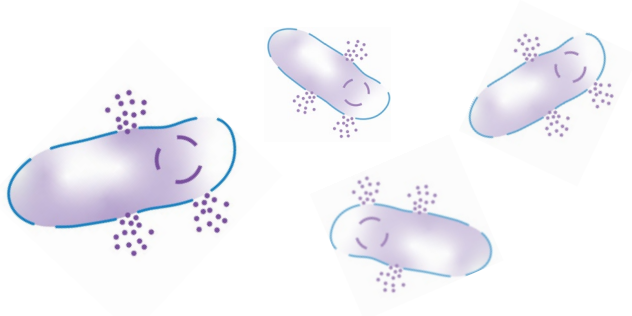
R327 interrupts bacterial cellular energetics via ATP Synthesis

Stage 3



Cellular division & non-dividing cell functions are disrupted

Stage 4



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

1 – Dilizia, M., 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[1]

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 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.

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

RECCE® 327 Activity Against *Escherichia coli*

- *E. coli* grows fast. Eukaryotic cells growing healthy, 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

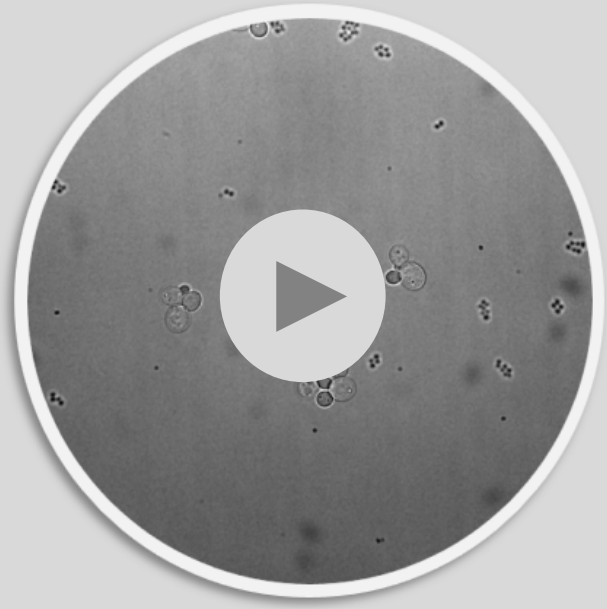
R327 (3,000 ppm)

eukaryotic cells ***E. coli***

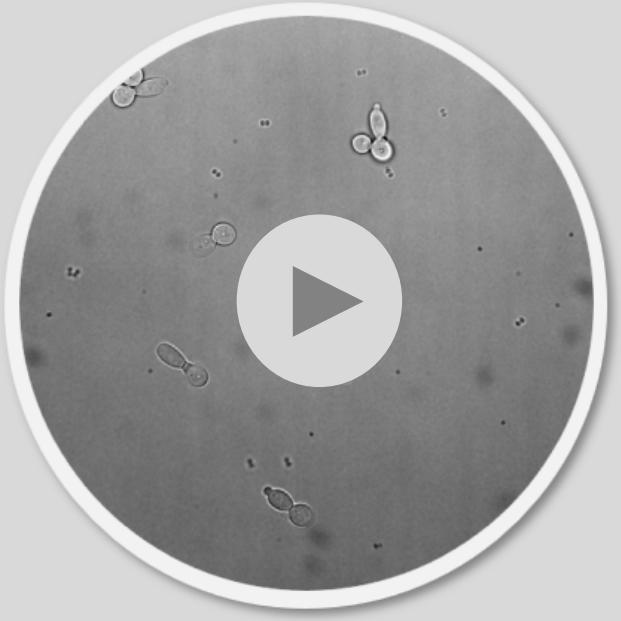
RECCE® 327 Activity Against *Staphylococcus aureus*

- *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)



eukaryotic cells ***S. aureus***

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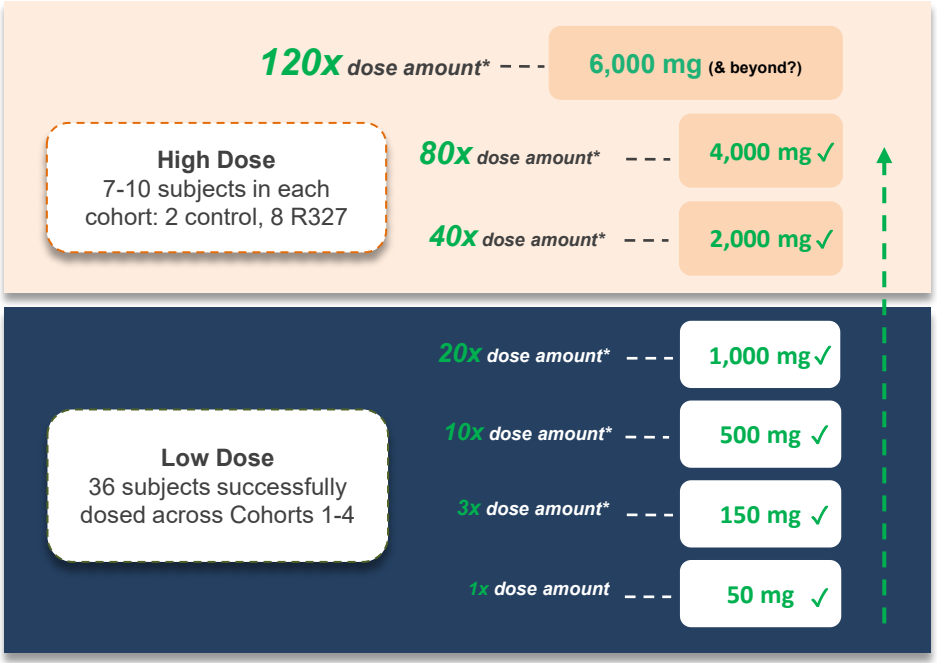
Phase I Human Clinical Trial

- **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.

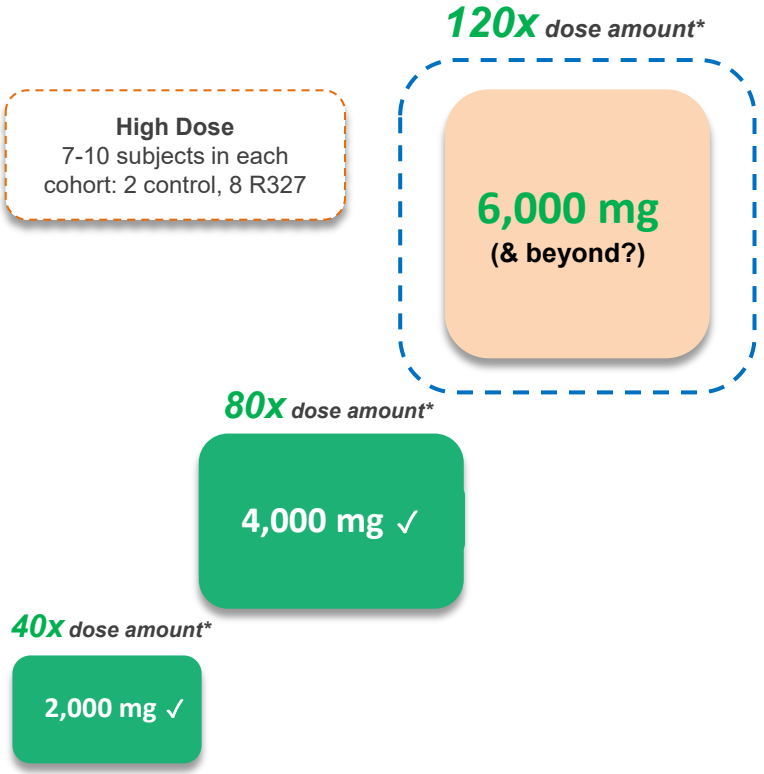


*Dose increase fold based off 50mg

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 (double the jump between prior two cohorts).
- **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 (need not repeat the now known).
- Next Phase preparations **well underway** (these now dose escalation increments welcomed bonus data sets).

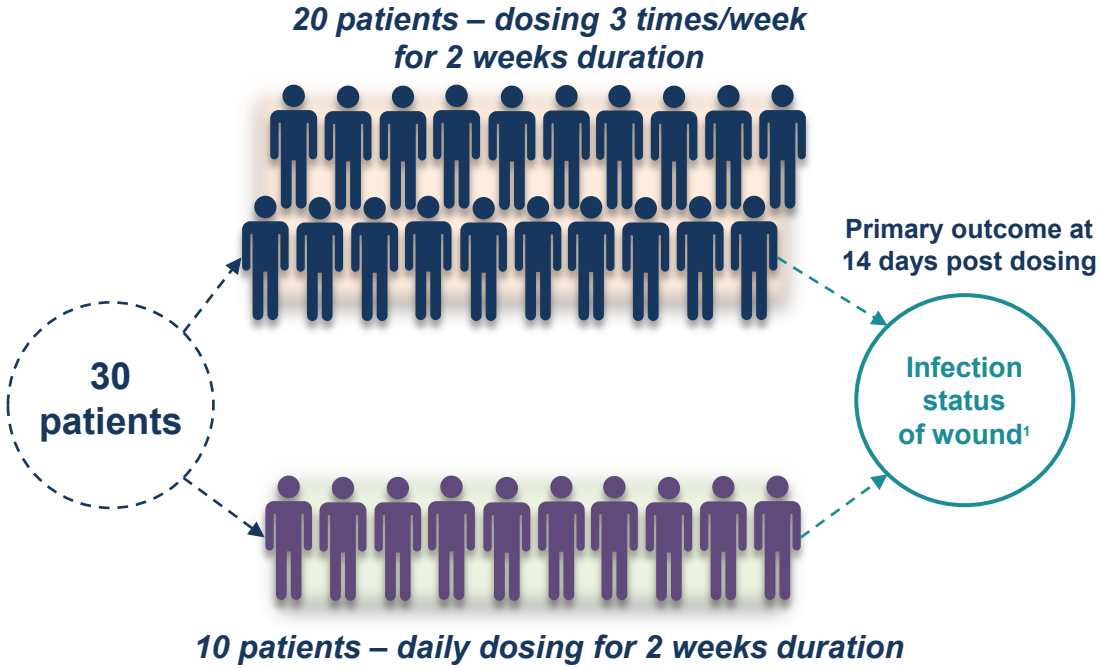


*Dose increase fold based off 50mg

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).



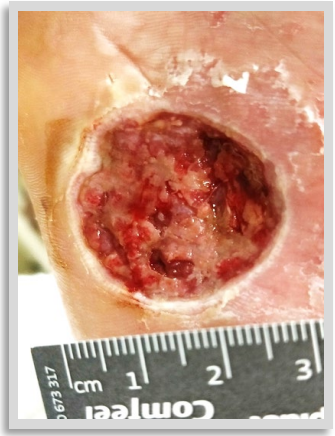
1 - Using the consensus clinical criteria of the International Wound Infection Institute

Topical RECCE® 327 – Phase I/II

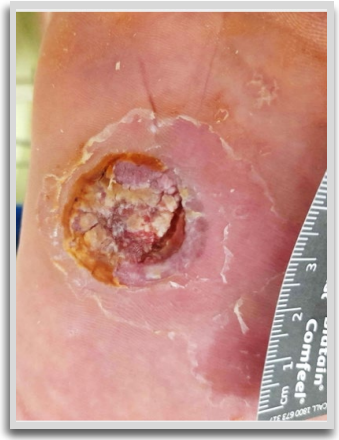
Patient examples from ongoing Burn Wound trial

- 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.**

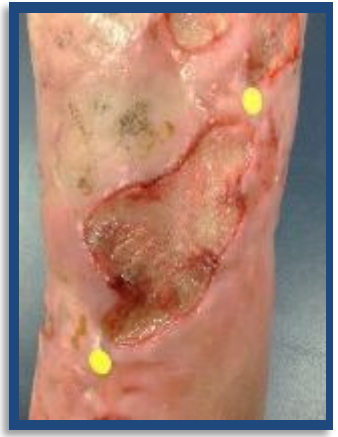
Study data now under-review for next-step considerations.



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

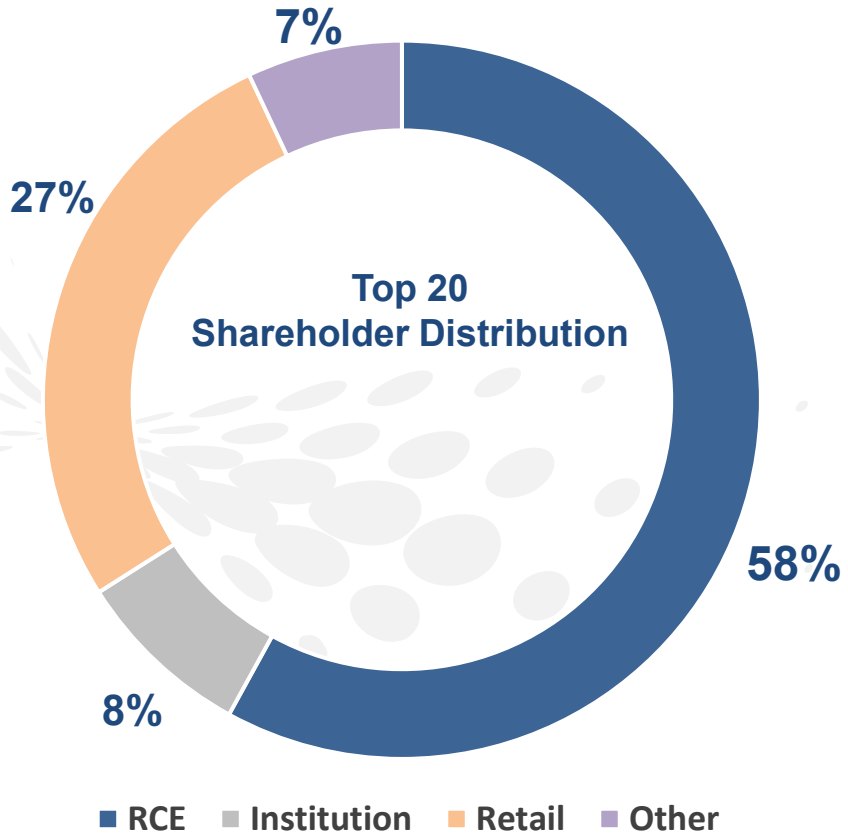
- Currently producing in **volumes to support** planned **Phase I & II clinical trials**.

- Facility built to pharmaceutical specification.
- Packaging and labelling to international 'tamper-proof' standards

Recce Pharmaceuticals Ltd – Capital Structure

Snapshot

Tickers	ASX:**RCE**, FSE:**R9Q**
Market Cap (approx.) Priced at $0.88	**AUD $156 million**
Cash and deposits 31 March 2022	**AUD $15.8 million**
Outstanding shares	**177.65 million**
Average daily volume 3 months	**150.97k**
Debt	**Nil**



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 1-6 dosed delivering further interim data imminent.*
***Topical Phase I/II human clinical study of R327 commenced Q4 2021**; further interim data imminent.*

***Robust financial position** to deliver clinical data.*

Thank you

James Graham
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