

ASX Announcement

Spark Plus Biotech Day Investor Presentation

SYDNEY Australia, 24 February 2023: 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 Biotech Day on Friday, 24 February 2023.

The event will feature presentations to investors from leading ASX-listed biotech companies. Recce Pharmaceuticals CEO, James Graham will be giving a 15-minute company presentation.



EMAIL JACK@SPARKPLUS.ORG
OR SCAN THIS QR TO REGISTER

Spark+
BIOTECH DAY

LEVEL 5
MARINA BAY
FINANCIAL CENTRE
TOWER 1

24TH FEB 2023
12 PM

FEATURING

Actinogen **IMUGENE** **Recce**
Developing Cancer Immunotherapies Pharmaceuticals

AdAlta **arōvella** **antisense**
next generation product therapeutics THERAPEUTICS THERAPEUTICS

SPONSORED BY

ASCENT **Baker McKenzie Wong & Leow**

Please find provided below a copy of the presentation slides to be presented by James Graham.

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



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Corporate Presentation

Disclaimer

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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



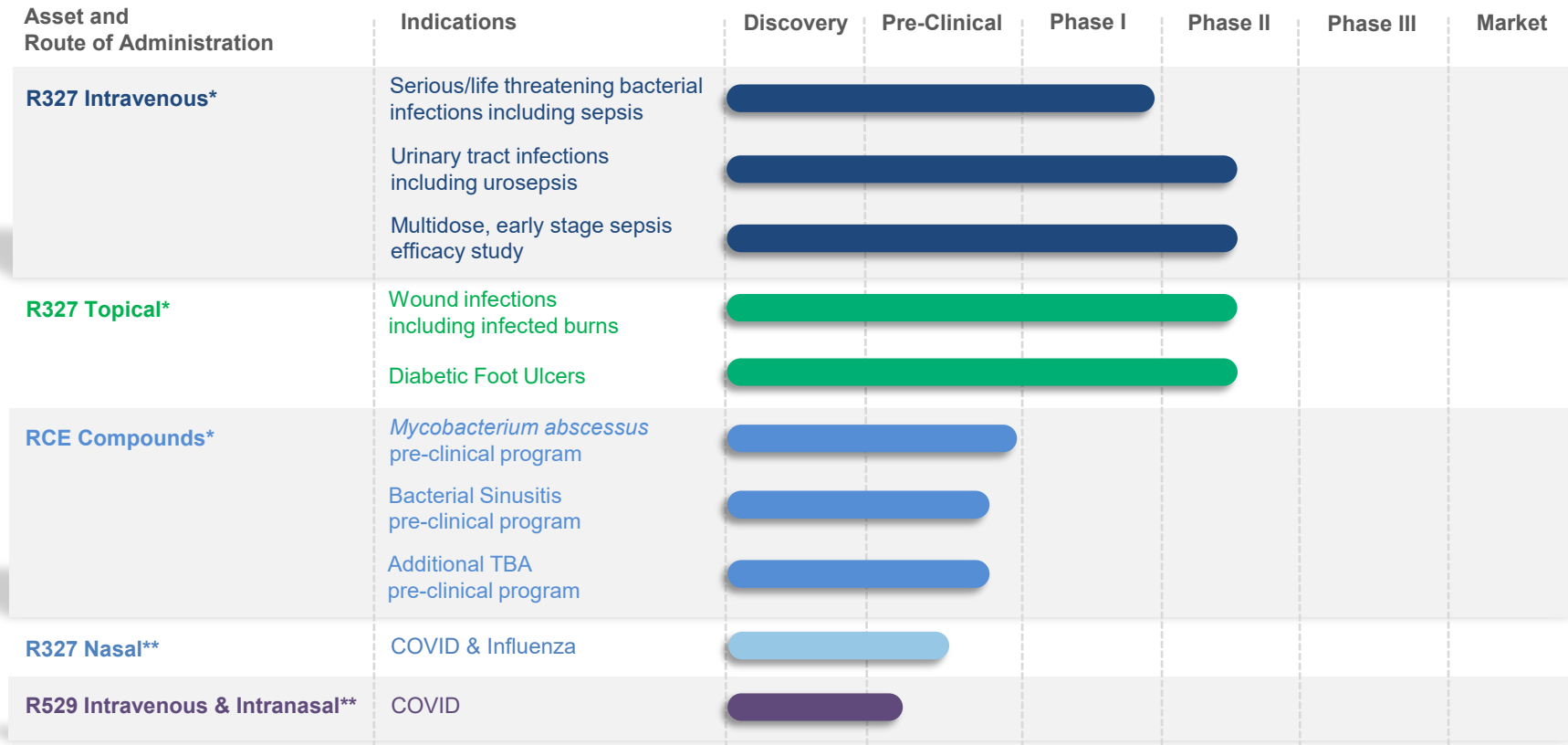
A Versatile Technology Platform

- 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



Strong Pipeline

Over Various Indications and Upcoming Inflection Points



*Anti-bacterial program

**Anti-viral program

Sepsis – it's a big problem!



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

What is Sepsis?

Sepsis is a life-threatening inflammatory response to infection that has spread in the body.

11 million sepsis-
related **deaths** recorded²



Economic Impact

Is the **most expensive condition to treat** in the last 8 years⁵.

Double the average cost per stay across all other conditions⁵.



One in three patients
who **die** in hospital
have sepsis³

Social Impact

Kills more people in the US than **prostate, breast cancer** and **HIV/AIDS** combined⁴.

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).

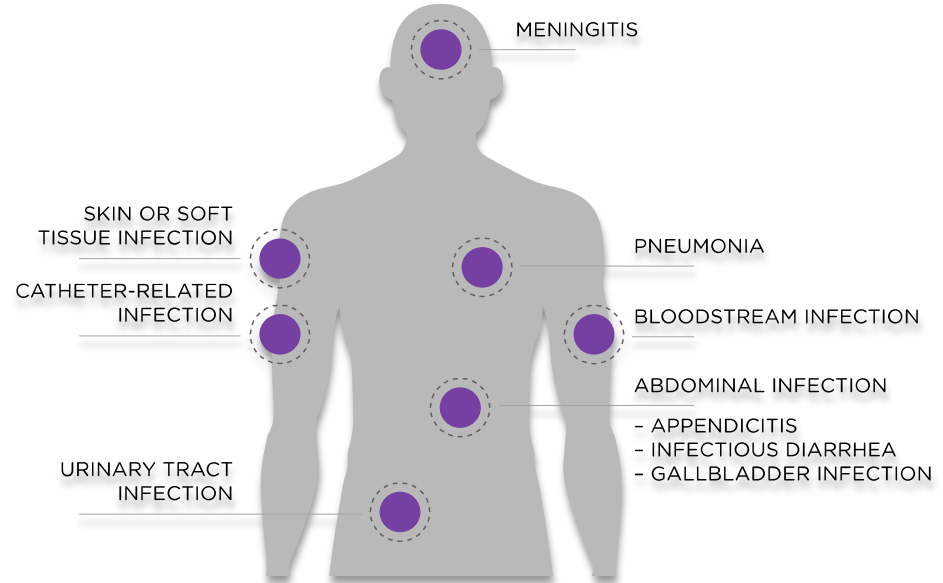


Current Treatment Paradigm

- 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



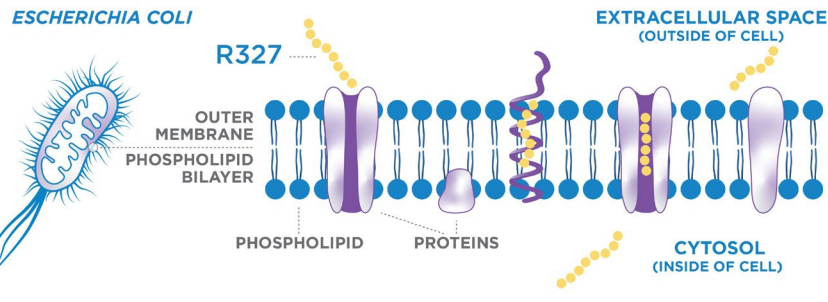
- **NO** pre-formed natural superbugs.
- Entirely **man-made** and designed with purpose.
- **Universal Mechanism of Action** - does not succumb to resistance.
- **Broad Spectrum capability** and maintains its activity even with repeated use.
- **Empowers clinicians** to confidently and quickly administer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

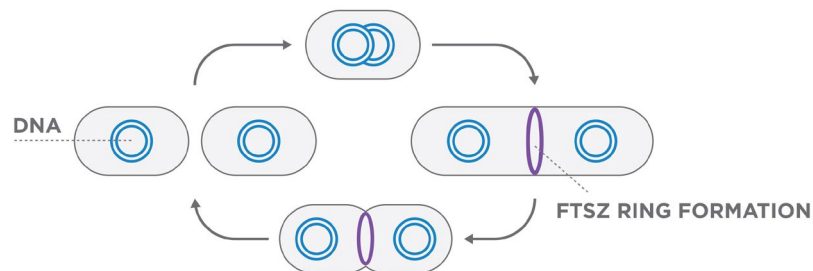
By Leading Experts in Bacterial MoA Analysis

Stage 1



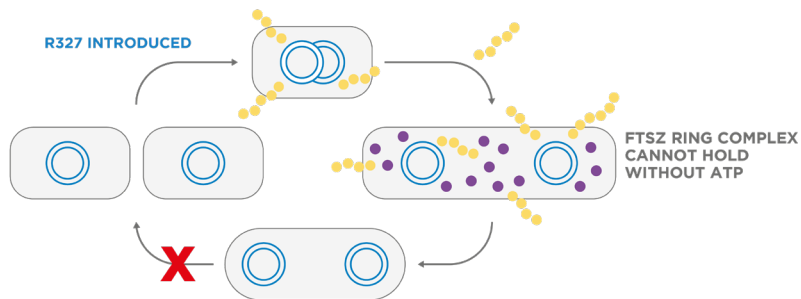
R327 permeabilizes cell membrane and enters the cell

Stage 2



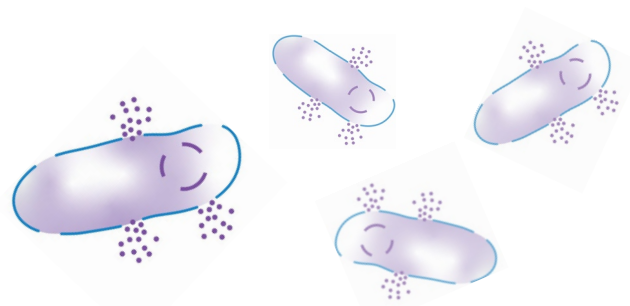
R327 interrupts bacterial cellular energetics via ATP Synthesis

Stage 3



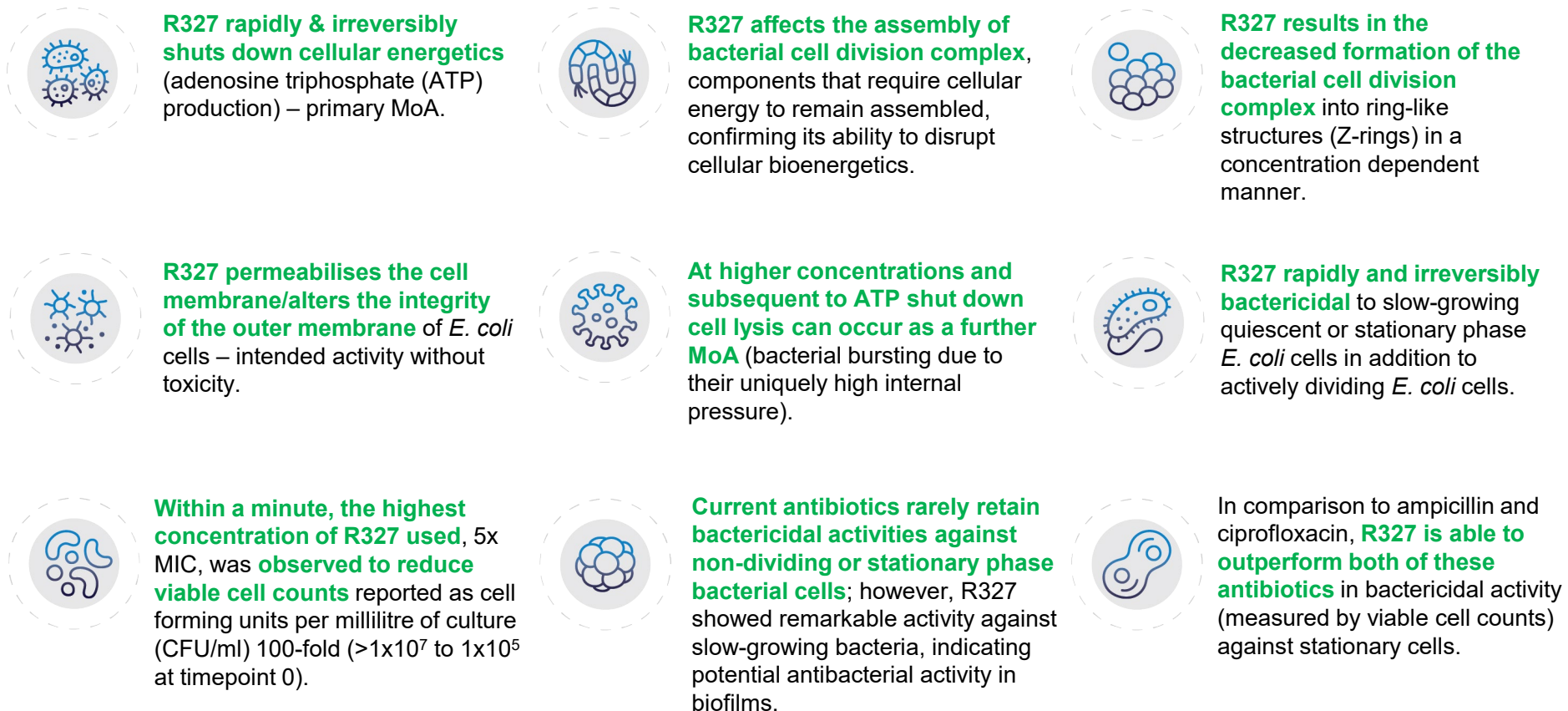
Cellular division & non-dividing cell functions are disrupted

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



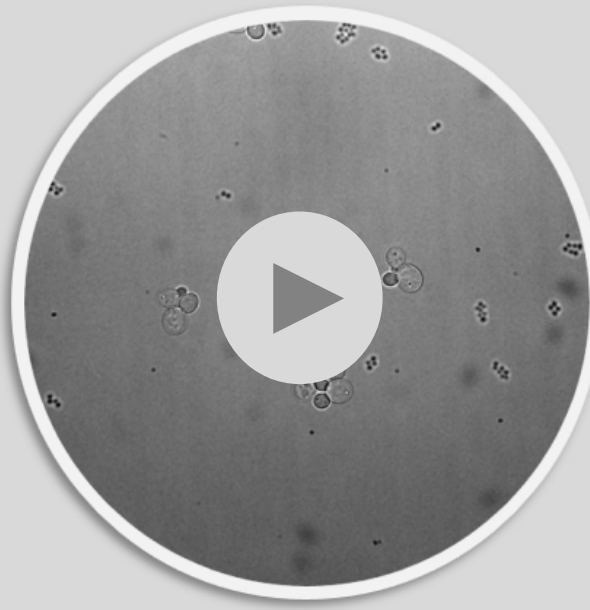
R327 (3,000 ppm)



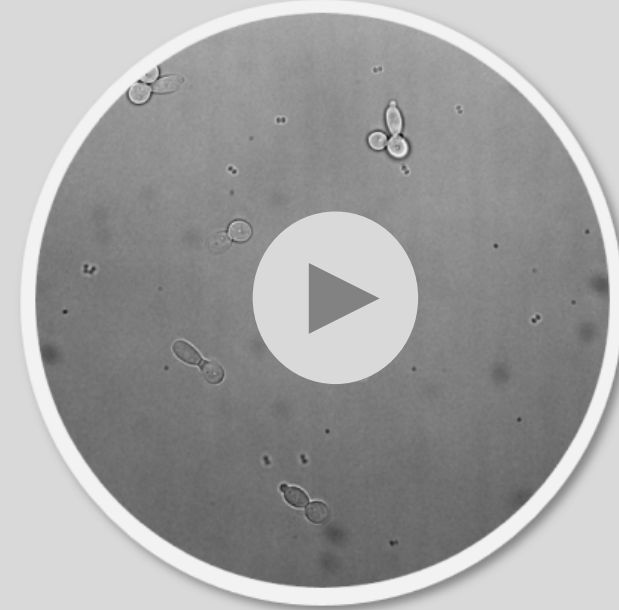
RECCE® 327 Activity Against *Staphylococcus aureus*

- *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

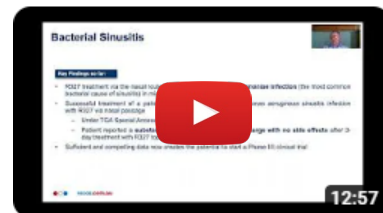


R327 (2,300 ppm)



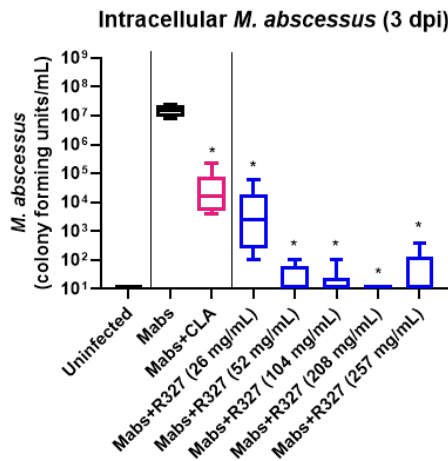
Pre-Clinical Study Outlook

- **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

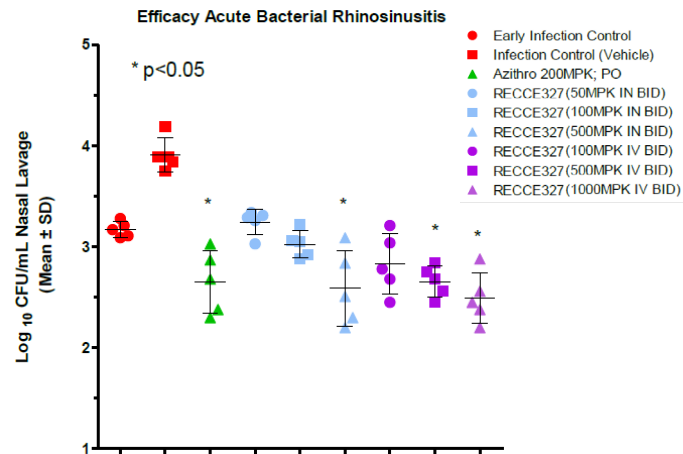
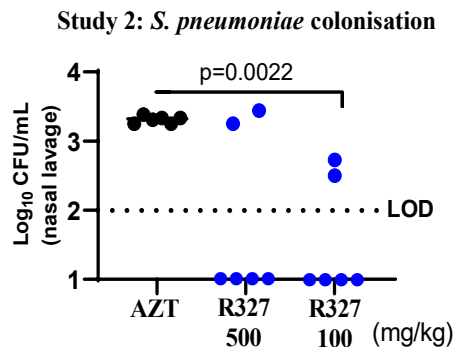


Dr Philip Sutton's Pre-Clinical Update

Mycobacterium abscessus Data



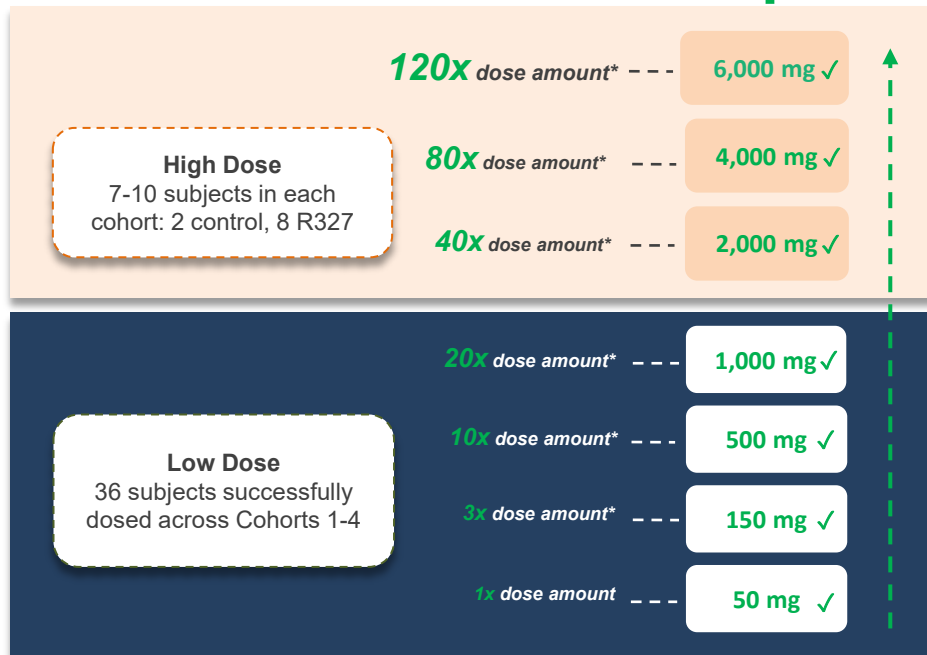
Bacterial Sinusitis Data



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



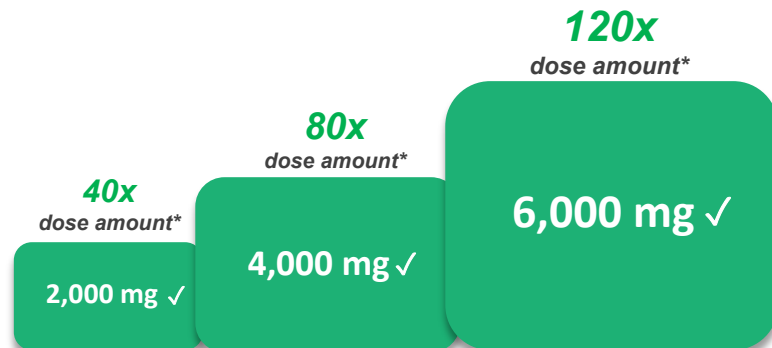
*Dose increase fold based off 50mg



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

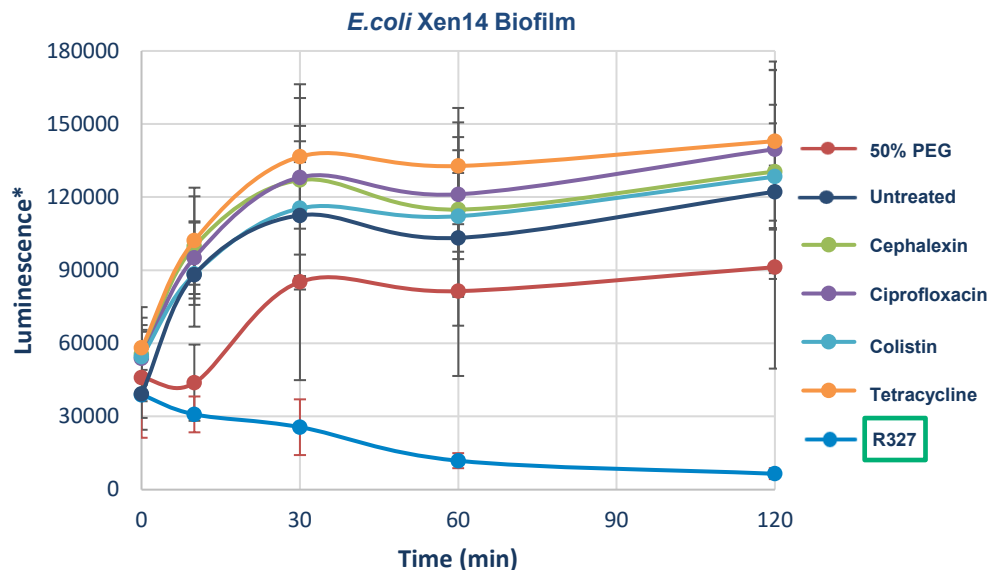


*As a result of **Phase I achievements**,
Phase II preparations are underway in
UTI, Kidney Infection Urosepsis and Sepsis*

*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.

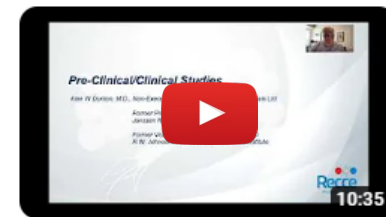
“R327 kills bacteria in conditions where other antibiotics are ineffective.”

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

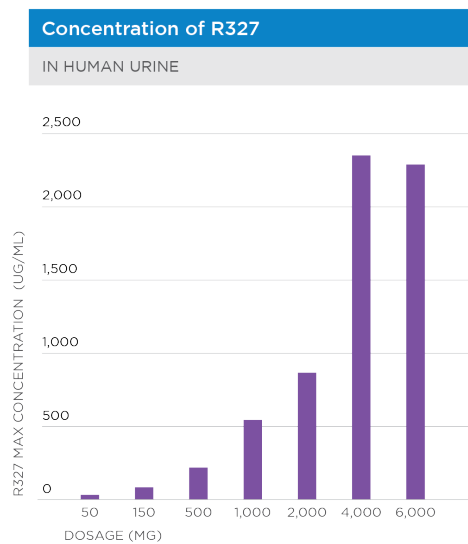
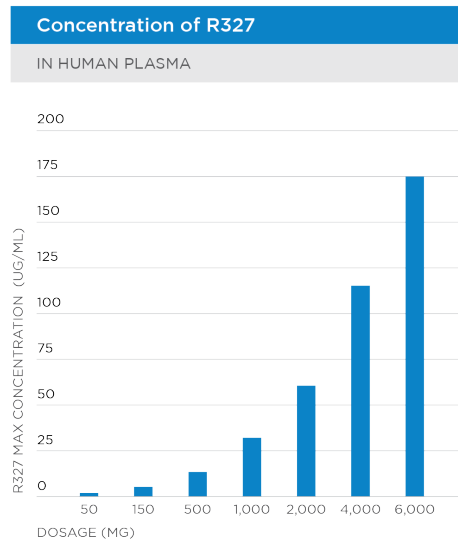
R327 is faster-acting against bacteria than other antibiotics – works quickly, without prolonged cellular exposure times required of other antibiotics (extended exposures commonly associated with systemic toxicity).



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

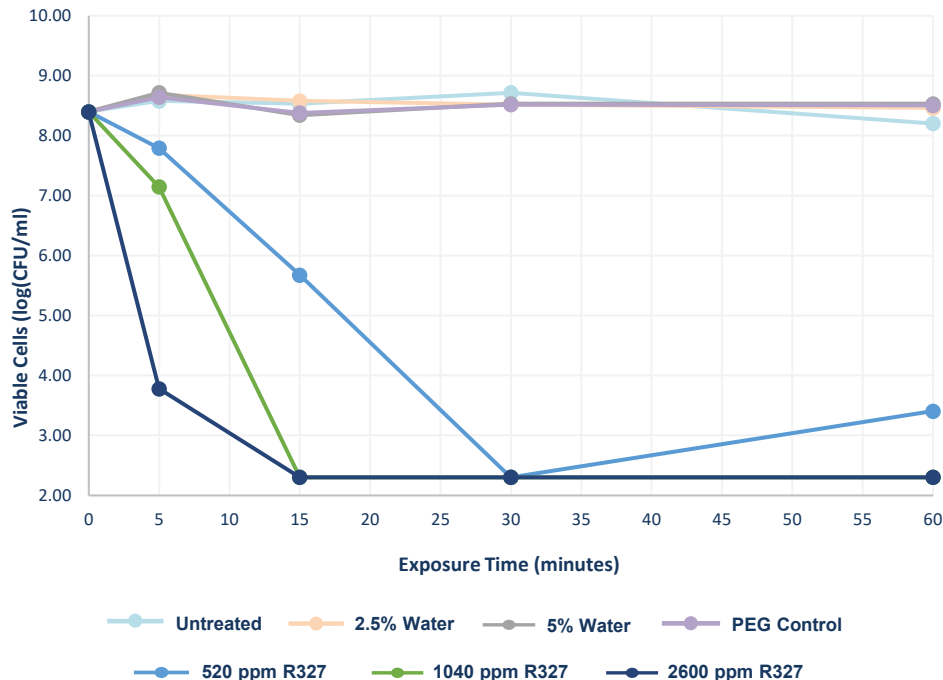
- **R327 primary route of elimination** appears to be through the kidney to the ureters and bladder.
- **High concentrations of R327** noted in the urine of Phase I healthy subjects.
- **Insight consistent** with pre-clinical *in-vivo* kidney and UTI bacterial infection studies.

- **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.



RECCE® 327 Kills Quickly in the Urine

E. coli ATCC 25922 Viable Cells Treated with RECCE® 327 in Urine + 10%LB



- **R327 in the presence of human urine was able to have a fast (near minutes effect against *E. coli* and irreversible**
- **Bacteria could not be ‘washed out’ and regrown**
- R327 capability starting from comparatively low concentrations
- Achieved 6-log reduction in viable cell count

Understanding logs (example of a small colony of 1 million MRSA bacteria)*

A 1-log kill reduces the colony to 100,000 MRSA bacteria after a 90% reduction

A 2-log kill reduces the colony to 10,000 bacteria after a 99% reduction

A 3-log kill reduces the colony to 1,000 bacteria after a 99.9% reduction

A 4-log kill reduces the colony to 100 bacteria after a 99.99% reduction

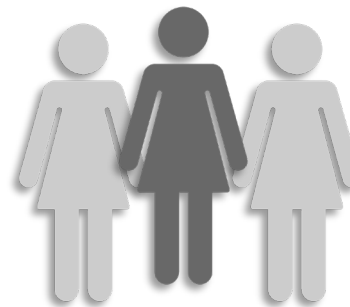
A 5-log kill reduces the colony to 10 bacteria after a 99.999% reduction

A 6-log kill reduces the colony to 1 MRSA bacterium after a 99.9999% reduction

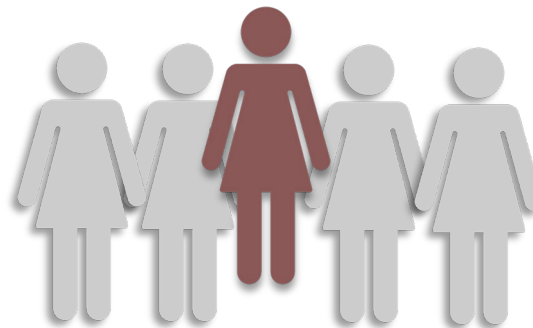


Background on UTIs

- **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 cefalotin (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.



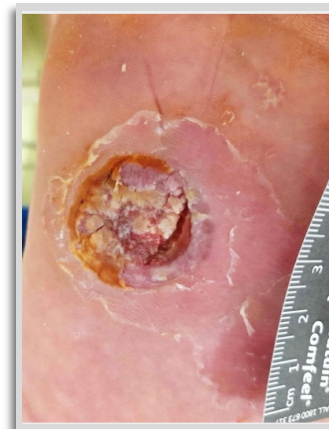
Topical RECCE® 327 – Phase I/II

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.

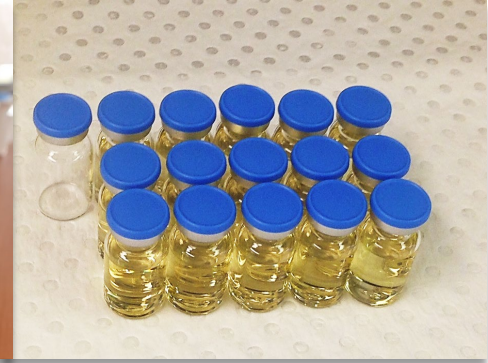
Recce's patent portfolio contains over 40 patents and patent applications in the world's major markets.

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.) **AUD \$102 million**
Priced at AUD \$0.572/share

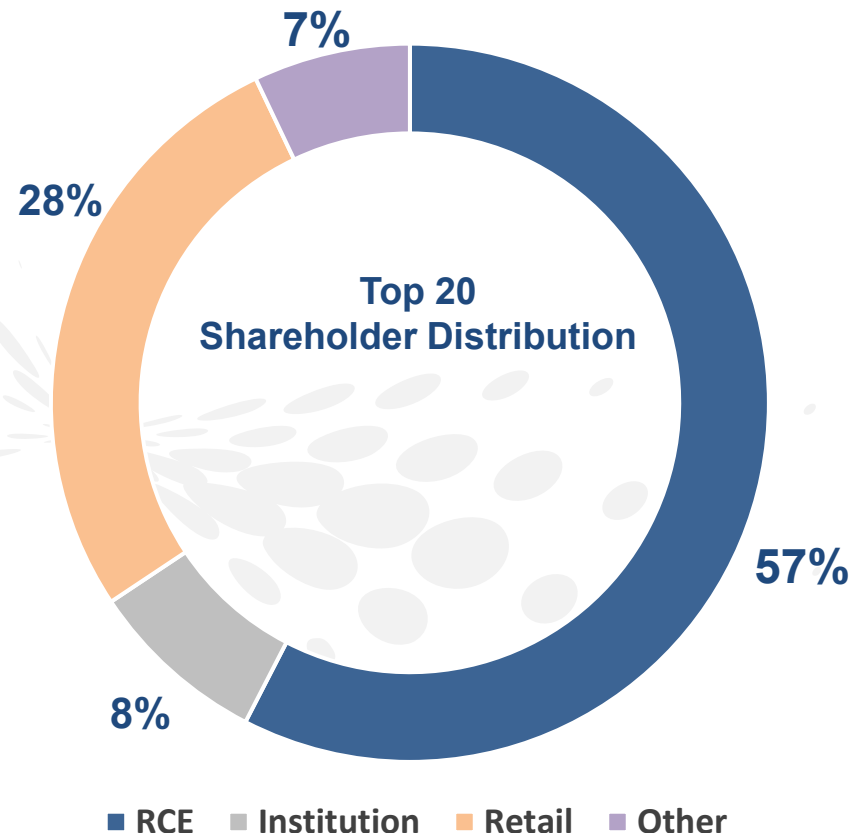
Cash and deposits* **AUD \$8.05 million****
30 January 2023

Outstanding shares **178.18 million**

Average daily volume **57.6k**
3 months

Debt **Nil**

**Includes cash balance of \$A1.84m and A\$6.21m from R&D rebate



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

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