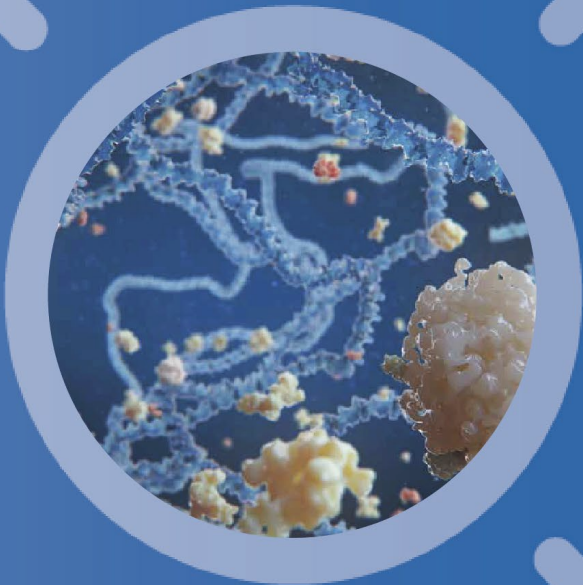




# ***A New Class of Synthetic Anti-Infectives***

**Equity Raising Presentation**



July 2024

ASX RCE | FSE R9Q

NOT FOR RELEASE TO US WIRE SERVICES OR DISTRIBUTION IN THE UNITED STATES

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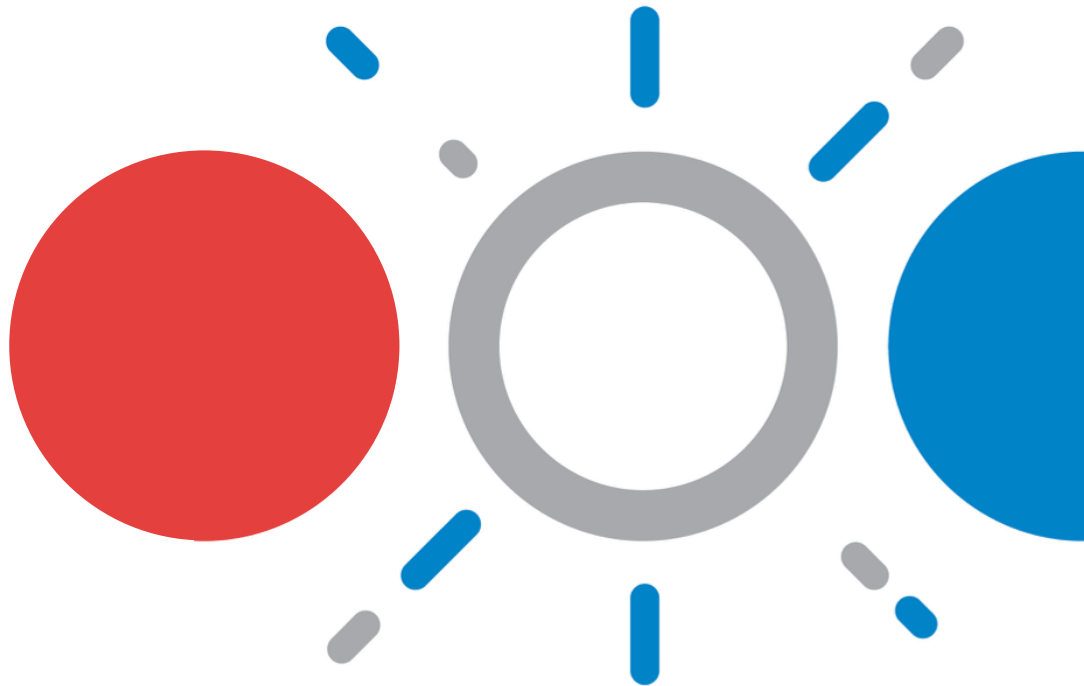
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# Executive Summary

|   |   |
|---|---|
| <b>Recce Pharmaceuticals overview</b>                                     | <ul style="list-style-type: none"><li>Recce Pharmaceuticals Ltd (<b>Recce</b>, or the <b>Company</b>) is developing a New Class of Synthetic Anti-Infectives designed to address the urgent global health problems of antibiotic-resistant superbugs and emerging viral pathogens</li><li>Recce's anti-infective pipeline includes three patented, broad-spectrum, synthetic polymer anti-infectives:<ul style="list-style-type: none"><li>RECCE® 327 as an intravenous and topical therapy being developed for the treatment of serious and life-threatening infections;</li><li>RECCE® 435 as an orally administered therapy for bacterial infections; and</li><li>RECCE® 529 for viral infections</li></ul></li><li>Recce's anti-infectives have the potential to overcome the hypercellular mutation of bacteria and viruses – the challenge of all antibiotics to date</li></ul> |
| <b>Key milestones over the next 12 months</b>                             | <ul style="list-style-type: none"><li>Recent successful completion of Phase I/II UTI/Urosepsis Rapid Infusion Clinical Trial</li><li>Launch Phase II UTI/Urosepsis Clinical Trial</li><li>Phase II Acute Bacterial Skin and Skin Structure Infection (ABSSSI) Clinical Trial (including Diabetic Foot Infections) approved, with data to follow</li><li>Commencement of US Department of Defence Burn Wound Program, including grant of US\$2.0 million (~AUD \$3.0 million)</li></ul>  |
| <b>Significant Indonesian opportunity to accelerate commercialisation</b> | <ul style="list-style-type: none"><li>MOU signed with PT Etana Biotechnologies Indonesia for collaboration in research and development, production, distribution and commercialisation of a first-in-class therapeutic agent for the treatment of bacterial infections</li><li>Indonesian Government is supportive, providing access to clinical facilities including hospitals and laboratories for Phase III studies</li><li>Opportunity for accelerated path to market with successful registrational Phase III trial the catalyst for revenues in FY2026</li></ul>  |
| <b>Capital raising to advance clinical trials for R327 and R327G</b>      | <ul style="list-style-type: none"><li>Up to ~A\$8.0 million institutional placement and ~A\$2.0 million SPP to raise up to a total of ~A\$10.0 million (the <b>Offer</b>)</li><li>Funds raised under the Offer will see Recce through to the completion of Phase II/III trials and potential for commercialisation in South East Asia with immediate catalysts to announce to market</li><li>Offer Price of A\$0.45 (<b>Offer Price</b>), which represents a:<ul style="list-style-type: none"><li>25.0% discount to the last traded price (\$0.60) on Friday, 28 July 2024</li><li>20.4% discount to the 10-day VWAP (\$0.565) as at Friday, 28 July 2024</li></ul></li><li>Post completion, Recce will have available funding of \$18.5 million*.</li></ul>   |

Note: Includes proceeds from the Offer (before costs) and \$8.5 million of cash as at 31 March 2024

# Equity Raising Details



# Equity Raising Overview

|                                 |   |
|---------------------------------|---|
| <b>Offer Structure and Size</b> | <ul style="list-style-type: none"><li>• Placement to institutional, sophisticated and professional investors to raise up to approximately A\$8.0 million (<b>Placement</b>)</li><li>• Following completion of the Placement, the Company intends to offer a Share Purchase Plan to raise up to an additional A\$2.0 million (<b>SPP</b>) (together with the Placement, the <b>Offer</b>)</li><li>• Approximately 22.2 million new fully paid ordinary shares (<b>New Shares</b>) to be issued under the Offer, representing ~10.9% of existing Recce shares on issue</li><li>• The Placement will utilise the Company's existing 15% placement capacity under ASX Listing Rule 7.1</li><li>• The Company reserves the right to accept oversubscriptions</li></ul> |
| <b>Offer Price</b>              | <ul style="list-style-type: none"><li>• New shares under the Placement will be issued at A\$0.45 per share (<b>Offer Price</b>), representing a discount of:<ul style="list-style-type: none"><li>◦ 25.0% to Recce's last closing price on Friday, 28 June 2024 of A\$0.60; and</li><li>◦ 20.4% to the 10-day volume weighted average price (<b>VWAP</b>) of A\$0.565 per share as at Friday, 28 June 2024</li><li>◦ 21.4% to the 30-day volume weighted average price (<b>VWAP</b>) of A\$0.573 per share as at Friday, 28 June 2024</li></ul></li></ul>   |
| <b>Ranking and Settlement</b>   | <ul style="list-style-type: none"><li>• New Shares issued under the Offer will rank pari passu with existing Recce shares on the date of issue</li><li>• Settlement of the Placement is expected to occur on Monday, 8 July 2024</li></ul>  |
| <b>Use of Proceeds</b>          | <ul style="list-style-type: none"><li>• Proceeds from the Offer will be used to advance clinical trials for intravenous use of R327, topical applications of R327G, IND-enabling activities and Phase III clinical activities in Indonesia</li><li>• Clinical activities in Indonesia have the potential to see Recce through to commercialisation of topical treatments using R327</li><li>• Please refer to pages 8 and 9 for further information</li></ul>   |
| <b>Lead Manager</b>             | <ul style="list-style-type: none"><li>• Ord Minnett Limited (<b>Ord Minnett</b>) is acting as Lead Manager to the Placement</li></ul>   |
| <b>Share Purchase Plan</b>      | <ul style="list-style-type: none"><li>• Post the completion of the Placement, Recce will conduct a SPP to eligible shareholders to raise up to an additional A\$2.0 million</li><li>• Further details relating to the SPP will be provided to eligible shareholders in Australia and New Zealand in due course</li></ul>  |

# Sources and Uses of Funds

| Use of Funds  | A\$            |
|---|----------------|
| Clinical trials (significant, unmet medical needs):   |                |
| <ul style="list-style-type: none"><li>Phase III Registrational Topical Clinical Trial in Indonesia</li><li>Phase II UTI/Urosepsis Clinical Trial</li><li>Phase II Acute Bacterial Skin and Skin Structure Infections (ABSSSI)</li><li>Commencement of US Department of Defense Burn Wound Program</li></ul> | \$7.5m         |
| Activities enabling Investigational New Drug application to FDA   | \$1.5m         |
| General working capital (operational costs delivering above) and offer costs  | \$1.0m         |
| <b>Total Uses</b>   | <b>\$10.0m</b> |

## Commentary

Capital raising of approximately \$10.0 million will fund Recce through to FY2026:

- Funds significant clinical trials in Australia, covering intravenous and topical treatments for UTI/Urosepsis and ABSSSI including Diabetic Foot Infections (DFI); as well as USA Department of Defence Burn Wound Program
- Continued development of pre-clinical portfolio
- Manufacturing expansion
- Provides necessary capital to see Indonesian clinical trials for topical treatments through to commercialisation

Strong cash position post equity raising:

- Existing Cash Balance of A\$8.5 million (31 March 2024)
- Pro-forma cash position of A\$18.5 million post capital raising<sup>1</sup>
- Additional, non-dilutive capital anticipated in 2024 and 2025 through US Department of Defense (A\$3.0 million) and R&D Advance (\$5.4 million) totaling \$8.7 million<sup>2</sup>

Notes: (1) Includes proceeds from the Offer (before offer costs) and \$8.5 million of cash as at 31 March 2024. (2) US Department of Defense Grant anticipated in Q3 2024. R&D advance from Endpoints Capital anticipated in January 2025.



# Detailed Use of Funds

Capital Raise will fund Recce through clinical trials to Q1 FY2026 with key catalysts ahead

FY2024

FY2025

FY2026

## Currently – Funded to Q2 FY2025

- ✓ Phase I/II Clinical Trial for the Treatment of Burn Wound Infections stage 1 data analysis was completed
- ✓ R327G indicated positive clinical response in the treatment of multiple antibiotic-resistant infections under TGA Special Access Scheme Category A
- ✓ MoU with PT Etana Biotechnologies Indonesia to work collaboratively on R&D, production, distribution and commercialisation of R327
- ✓ R327 Phase I/II UTI/Urosepsis Rapid Infusion Clinical Trial - safe and well tolerated at faster infusion rates 20min for 2,500mg and 3,000mg
- ✓ Phase II Acute Bacterial Skin and Skin Structure Infections (ABSSSI) including Diabetic Foot Infections (DFI) Clinical Trial Approved
- ✓ Completion of Phase I/II UTI Rapid Infusion ex vivo trial in subjects – data will predict efficacy in UTI/Urosepsis Phase II trial

## Post Capital Raise – Funded to Q1 FY2026

- ❑ Launch Phase II UTI/Urosepsis Clinical Trial (with data readouts throughout)
- ❑ Phase II ABSSSI trial with data readouts throughout
- ❑ Launch Phase III Registrational Topical Clinical Trial in Indonesia
- ❑ Commencement of US Department of Defence Burn Wound Program – in concurrence with US Department of Defence Burns Grant of USD \$2.0 million (~AUD \$3.0 million)
- ❑ File Investigational New Drug application for R327 in the USA

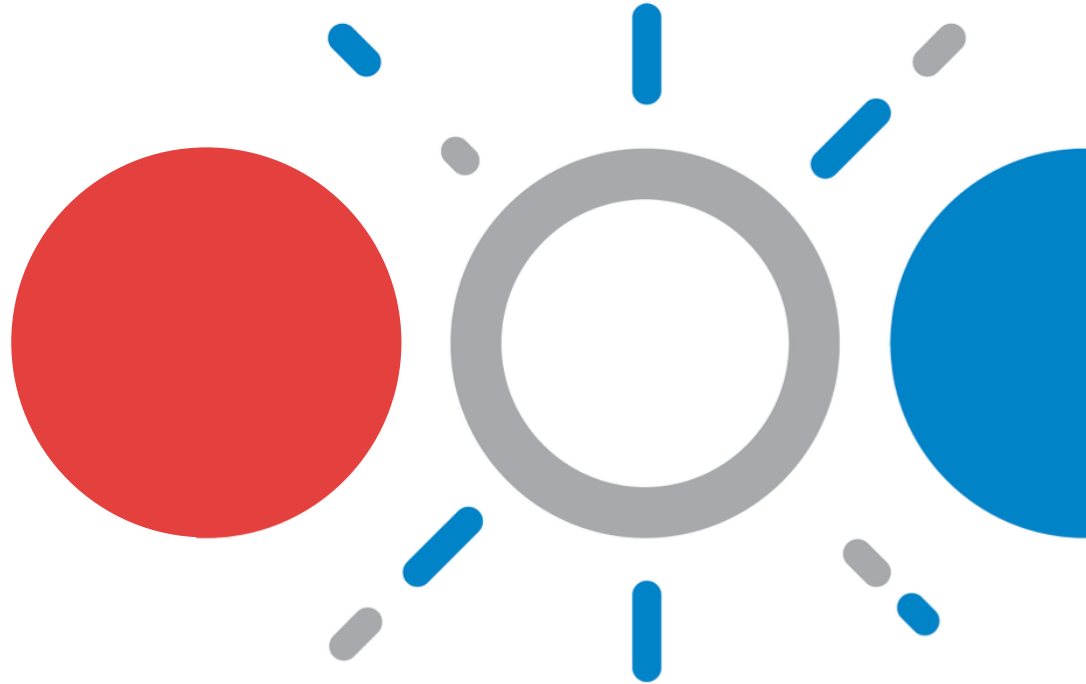


# Equity Raising Timetable

| Event   | Date                           |
|---|--------------------------------|
| <b>Placement</b>                                      |                                |
| Trading Halt and Placement Opens                      | Pre-market Monday, 1 July 2024 |
| Placement Closes                                      | 5:00pm, Monday, 1 July 2024    |
| Announcement of Completion of Placement               | Tuesday, 2 July 2024           |
| Settlement of Placement                               | Monday, 8 July 2024            |
| Allotment of New Shares under the Placement           | Tuesday, 9 July 2024           |
| <b>Share Purchase Plan</b>                            |                                |
| SPP Record Date                                       | 7:00pm, Monday, 1 July 2024    |
| SPP Offer Booklet made available and SPP Offer opens  | Wednesday, 10 July 2024        |
| SPP Offer closes                                      | 5:00pm Wednesday, 31 July 2024 |
| Announcement of Share Purchase Plan results           | Monday, 5 August 2024          |
| Allotment of new shares under the Share Purchase Plan | Tuesday, 6 August 2024         |

*This timetable is indicative only and subject to change. The Company reserves the right to vary the above dates and times, subject to ASX Listing Rules and the Corporations Act 2001 and other applicable laws. All times and dates are in reference to Sydney, Australia time.*

# Company Overview



# About Recce Pharmaceuticals Ltd

*Recce Pharmaceuticals Ltd (ASX: RCE, FSE: R9Q) is developing a new class of Synthetic Anti-Infectives*



- Australian clinical-stage biotech company, with a United States presence
- **Qualified Infectious Disease Product designation** – 10 years of market exclusivity plus fast-track approval\*
  - RECCE® 327 (main product candidate) included on **The Pew Charitable Trusts Global New Antibiotics in Development Pipeline** as the **world's only synthetic polymer, sepsis drug candidate in development**
  - The **World Health Organization** added RECCE compounds to its list of antibacterial products in clinical development for priority pathogens
- Multiple clinical indications and formulations in Phase I and II **addressing unmet medical needs**

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

# Company Overview

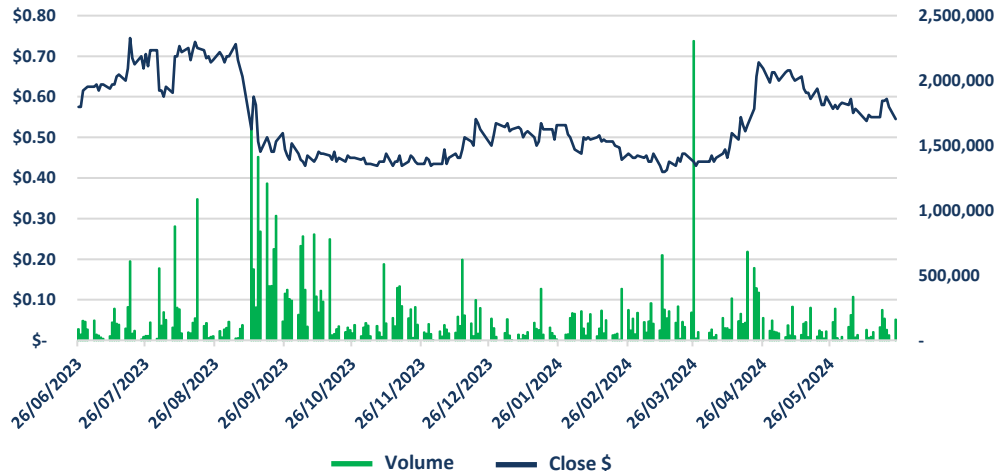
Recce Pharmaceuticals Ltd is a clinical-stage biotech company with a new class of novel synthetic anti-infectives

## Capital Structure – June 2024

|                               |                      |
|-------------------------------|----------------------|
| ASX & FSE Code                | RCE, R9Q             |
| Share Price                   | AUD \$0.60           |
| 3-Month Average Volume        | 141.72k              |
| Shares on Issue               | 203.99 million       |
| Unlisted Options (Avg \$1.54) | 13.9 million         |
| Market Capitalisation         | AUD \$122.39 million |
| Cash at Bank                  | AUD \$8.52 million*  |
| Top 20 Shareholders           | 51%                  |
| Debt                          | Nil                  |

\*AUD \$8.52m cash at bank as of 31 March 2024 (4C)

## RCE Share Price and Volume Chart – 12 Months (price shown in AUD)



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**AUD \$11,178,965** received as an R&D Advance with Endpoints Capital (Endpoints) capturing Recce's Research and Development (R&D) Tax incentive for FY23/24 & FY25.



**Australian Government awarded AUD \$54,947,284 (USD \$37,043,433) Advanced Overseas Finding\*** across RCE infectious disease portfolio\*\*



Proprietary **first-in-class, broad-spectrum anti-infectives** against bacteria

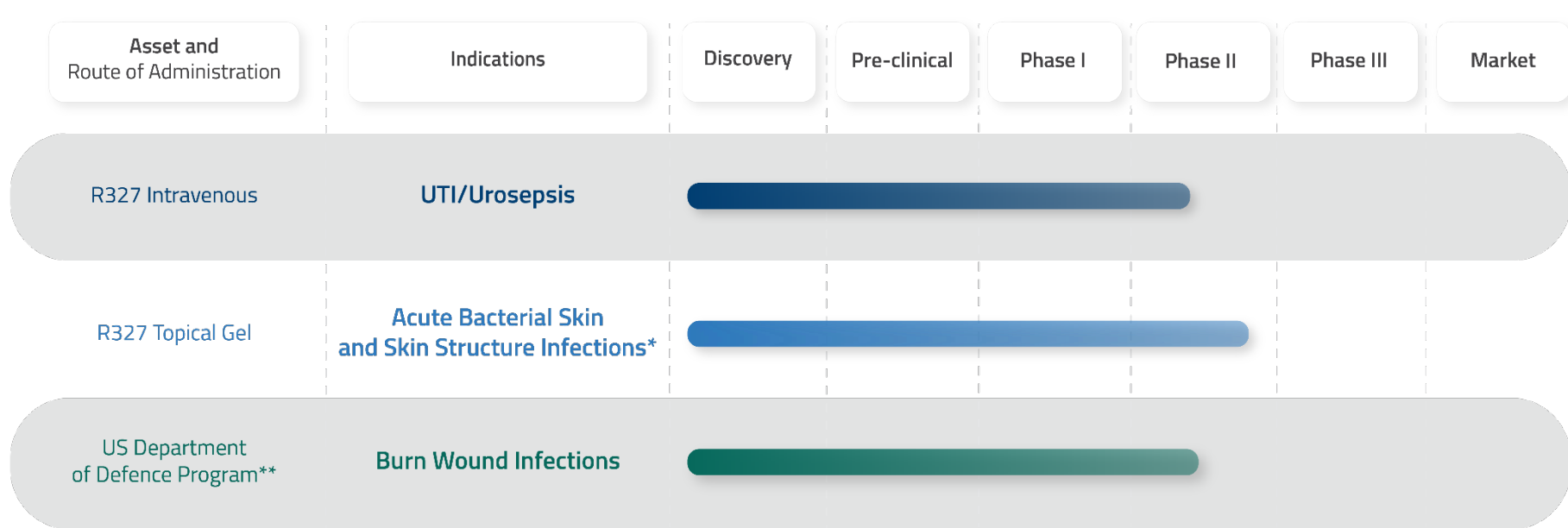


Multiple clinical indications and formulations in Phase I and Phase II addressing unmet medical needs: **Sepsis, UTI/Urosepsis, Burn Wounds and Acute Bacterial Skin and Skin Structure Infections (ABSSSI), including Diabetic Foot Infections**

\*\*The Advanced Finding is a binding, underwritten guarantee provided by the Australian Government, which affirms the Company's R&D activities are of national interest and extends the 43.5% R&D rebate from locally, to cover those undertaken by the Company anywhere in the world for a period of three years. This finding does not constitute a grant, or an upfront payment of the amount awarded

# Strong Pipeline

Over Various Indications and Upcoming Inflection Points



\* Including postoperative infection, wound infections and diabetic foot infections

\*\* The US Department of Defence has recommended R327 Gel (R327G) as a topical treatment for Burn Wound Infections for grant funding of USD \$2.0 million (AUD \$3.0 million)

# Robust Worldwide Intellectual Property Portfolio

Patent portfolio containing over 40 patents and patent applications in the world's major markets

| Filed     | Patent Family 1 | Expiry | Patent Family 2 | Expiry | Patent Family 3 | Expiry | Patent Family 4 | Expiry |
|-----------|-----------------|--------|-----------------|--------|-----------------|--------|-----------------|--------|
| Australia | ✓               | 2028   | ✓               | 2037   | ✓               | 2037   | ✓               | 2041   |
| USA       | ✓               | 2029   | ✓               | 2037   | ✓               | 2037   | Pending         | -      |
| Europe    | ✓               | 2028   | ✓               | 2037   | ✓               | 2037   | Pending         | -      |
| 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   | Pending         | -      |
| China     | ✓               | 2028   | ✓               | 2037   | ✓               | 2037   | Pending         | -      |
| HK        | Pending         | 2028   | Pending         | 2037   | ✓               | 2037   | Pending         | -      |
| Israel    | -               | -      | -               | -      | -               | -      | ✓               | 2041   |
| Canada    | -               | -      | -               | -      | -               | -      | ✓               | 2041   |

**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.

**Family 4** relates to Process for Preparation of Biologically Active Copolymer, other Patent Cooperation Treaty countries (pending/granted)

# Board and 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 Nighthawk Biosciences (NYSE: HHWK). With extensive experience in the international commercialisation of pharmaceutical technologies, **Dr Prendergast has been responsible for the approval of three new drug applications.**



**James Graham – Managing Director & Chief Executive Officer**

*BCom (Entrepreneurship), GAICD*

Six years as former Executive Director and extensive experience in marketing, business development and commercialisation of early-stage technologies with global potential. **Mr Graham has served on Recce's Board of Directors for six years and has invested in almost every capital raise to date** with a focus on expanding Recce's commercial opportunities and clinical initiatives.



**Dr Alan Dunton – Chief Medical Advisor & Non-Executive Director**

*BSc (BioChem) Hons, M.D. (NYU)*

US based, Director of Palatin Technologies. Over three decades of senior pharmaceutical experience incl. President and MD of Janssen Research Foundation (Johnson & Johnson). **Dr Dunton has advanced a number of blockbuster antibiotics** through regulatory review and commercialisation at Fortune 500 companies including Roche. **Dr Dunton has been responsible for the approval of approximately 20 New Drug Applications;** an amalgamation of prescription and OTC products



**Michele Dilizia – Executive Director & Chief Scientific Officer**

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

Co-inventor and qualified medical scientist with a specialisation in medical microbiology and regulatory affairs. **Ms Dilizia successfully co-led the research and development of Recce's suite of anti-infective compounds,** resulting in a portfolio of granted patents across the globe, including a Qualified Infectious Disease Product designation with the U.S. FDA.



**Dr Justin Ward – Executive Director & Principal Quality Chemist**

*BSc (Chem), PhD (Chem), M Pharm, MRACI, CChem*

A quality control expert who has worked with leading pharmaceutical companies. He previously held a technical role with Pfizer, involving providing data for the regulatory submissions to the FDA and TGA. Dr Ward is bringing Recce's research and development and manufacturing up to US FDA requirements.



**Alistair McKeough – Non-Executive Director**

Alistair is a qualified lawyer and specialises in complex commercial matters that require careful and strategic planning. Mr McKeough has extensive experience advising ASX-listed companies and their directors and is a member of the University of New South Wales Law Advisory Council.



# The Need for a New Class of Antibiotics: Synthetic Anti-Infectives

On-track to be the only *global clinical stage company* whose drug is shown to be *efficacious* against the full suite of *ESKAPE pathogens*.



- **NO** pre-formed natural superbugs.
- Very broad-spectrum coverage of bacteria with **no signs of resistance**.
- **Universal Mechanism of Action** - does not succumb to resistance.
- **Broad Spectrum capability** and maintains its activity even with repeated use.
- **Extremely rapid onset of effect – measured in minutes** as compared to hours for typical antibiotics.
- **Multiple formulations available** – intravenous, topical liquid, topical gel and aerosol for inhalation or intranasal.

# Large Addressable Market

The global diabetic foot infection (DFI) and sepsis market is worth in excess of \$US9.5 billion

## Global Diabetic Foot Infections (DFI) Market

- The DFI treatment market is estimated to be worth ~US\$5.2 billion<sup>1</sup>
- Initially targeting Indonesian market valued at ~US\$189m where DFI impacts 11% of the population<sup>2</sup>
- Significant near term opportunity for Recce with registrational Phase III trials anticipated to be completed in FY26 paving the way for future revenues
- Indonesian approvals provide access to the broader Asia Pacific market worth ~US\$1.0 billion per year<sup>3</sup>

US\$5.2B

Global DFI treatment market<sup>1</sup>

## Global Sepsis Market

- Global sepsis treatment market estimated to be worth ~US\$4.6 billion in 2023 and is projected to grow at a CAGR of 5.5% to reach ~US\$13.7 billion by the end of 2030<sup>4</sup>
- Recce is initially targeting US and Australian markets worth in excess of US\$1.5 billion<sup>4</sup>

US\$4.6B

Global sepsis market<sup>4</sup>

Significant additional market opportunities exist in the broader anti-infectives market, estimated to be worth ~US\$136.9 billion with Recce already exploring opportunities in burn wound infections, skin and soft tissue infections post operation<sup>5</sup>.

Source: (1) Grand View Research, Diabetic Foot Ulcer Treatment Market Size, 2023 (2) Diabetes Atlas, International Diabetic Federation and Prof EM Yunir, Faculty of Medicines, University of Indonesia. (3) Business Market Insights, Asia Pacific Diabetic Foot Ulcer Market, 2021 (4) ResearchandMarkets, Global Sepsis Therapeutics, 2024 (5) Grand View Research, Anti-Infective Agents Market Size, 2023

# Sepsis – it's a big problem!

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

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>.



**48.9 million**

Cases of **sepsis** recorded worldwide<sup>1</sup>

Kills more people in the US than **prostate, breast cancer** and **HIV/AIDS** combined<sup>4</sup>.



**11 million**

Sepsis **related deaths** recorded<sup>2</sup>

**Currently no drug therapies specifically for the treatment of sepsis**<sup>6</sup>.



**1 in 3**

Patients **who die in hospital** have sepsis<sup>3</sup>

Notes: (1), (2), (3) *The Lancet*. (4) *BioMed Central*. (5) *University of Texas*. (6) *International Medicine Journal RACP*

# Sepsis – Patient Journey



## Patient Presents at the Hospital

- 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)**.
- In approximately **30% of all septic patients the infectious focus is localised in the urogenital tract**.



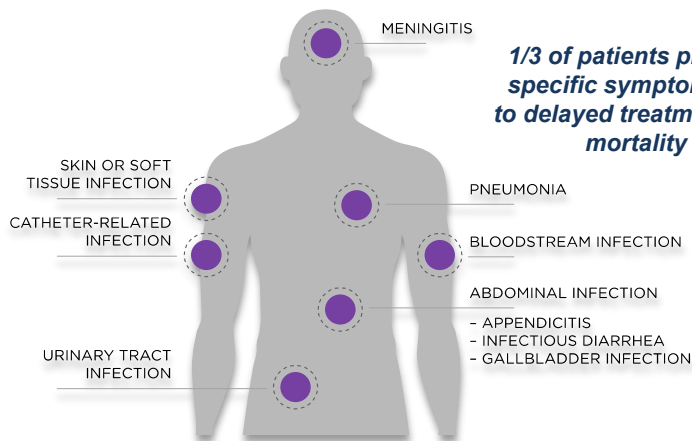
## The Infection

- The most common pathogen causing Urinary Tract Infections (UTIs) is ***E. coli* with 90%**
- **Urosepsis** is **sepsis** caused by **infections** of the urinary tract, bladder and kidney.
- More than **92%** of bacteria that cause UTIs are **resistant to at least one common antibiotic**, and almost 80% are resistant to at least two.



## Current Treatment Paradigm

- Introducing broad-spectrum antibiotic (s)
- Running antibiograms
- Adjusting antibiotics based on antibiogram results



*1/3 of patients present non-specific symptoms, leading to delayed treatment and high mortality rate.*

# Independent Study Undertaken on R327 MoA<sup>1</sup>

*By Leading Experts in Bacterial MoA Analysis*

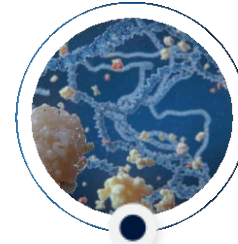
- Novel mechanism which targets rapid access to and shut down of bacterial energy production (ATP) **which results in bacterial death of both active and resting bacteria.**
- **Activity of R327 is measured in minutes** not hours like most other antibiotics.
- **Host cells not negatively impacted** by RECCE<sup>®</sup> compounds.
- Linnaeus Biosciences MoA studies of R327; presented in abstract.

Stage 1



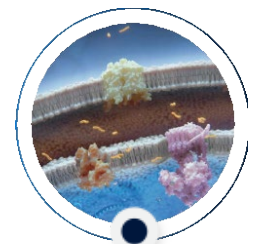
R327 arrests cell growth and permeabilizes cell membranes

Stage 3



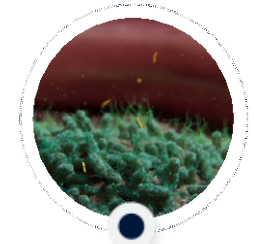
R327 inhibits major bacterial metabolic pathways including protein synthesis and cell division

Stage 2



R327 disrupts bacterial cellular energetics, depleting ATP

Stage 4



R327 is rapidly and irreversibly bactericidal

Note (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

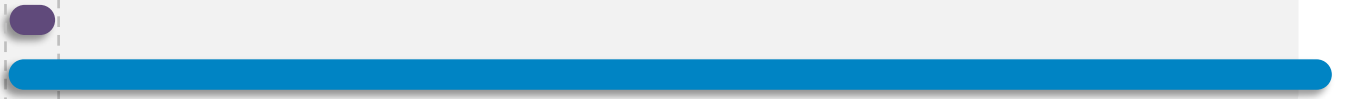
# RECCE® 327 Maintains Activity

Number of repeats before displaying loss of antibiotic activity

Bacteria\*

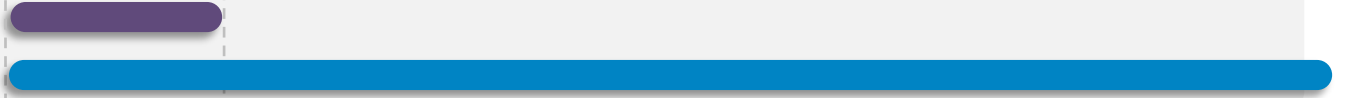
2 4 6 8 10 12 14 16 18 20 22 24 25 →

*Escherichia coli*

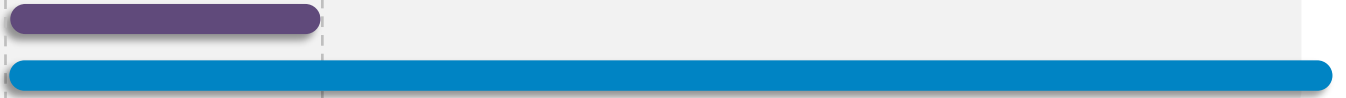


25 repeats at time of discovery was sufficient for PCT patent applications, with no sign of resistance.

*Pseudomonas aeruginosa*



*Staphylococcus aureus*



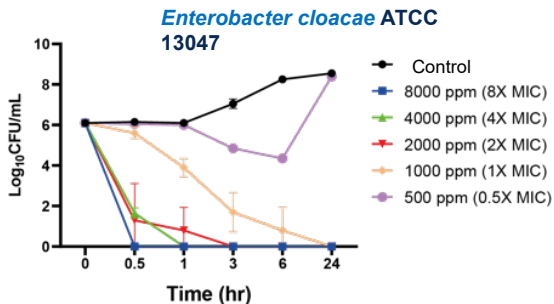
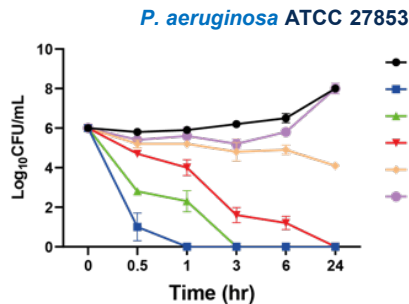
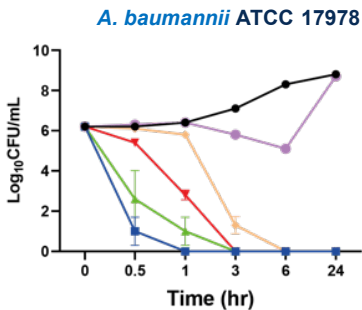
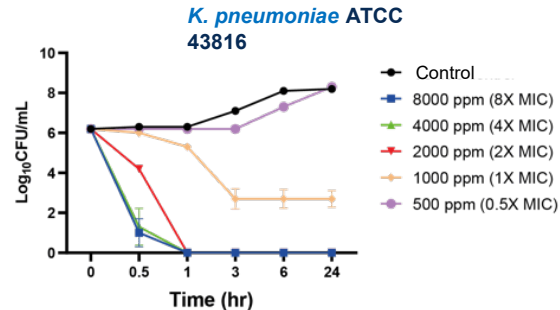
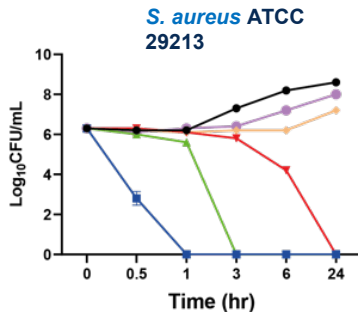
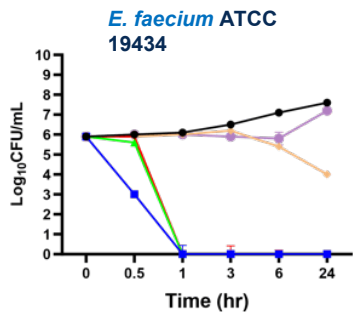
\*Antibiotic Sensitive Strains

Amoxicillin loses activity after a number of repeats; >25 repeats RECCE® 327 DOES NOT

● Amoxicillin

● RECCE® 327

# Bactericidal Effect of RECCE<sup>®</sup> 327 on ESKAPE Pathogens

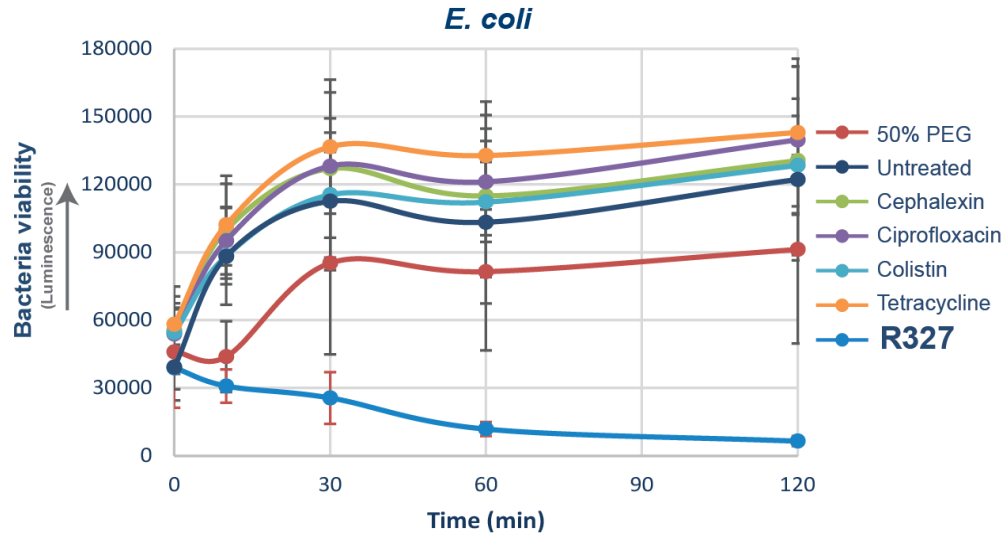


• Average time-kill curves of R327 at various concentrations against strains of ESKAPE pathogens (tested in duplicate)

• Time-kill study was performed to determine the bacterial killing effect of R327 at a total of five concentrations, ranging from 0.5X to 8X, MIC and to measure killing kinetics of treatment with R327 against each strain.

# 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).**

\*Xen14 (a reduction in luminescence correlates with decrease in cell viability). All compounds used at 2X Minimum Inhibitory Concentration (MIC)

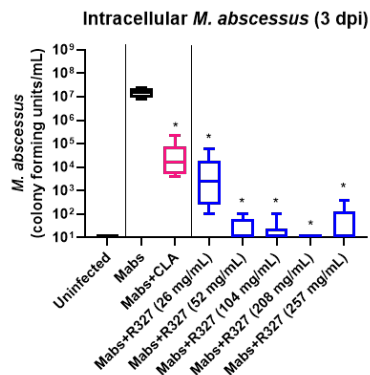


# RECCE® 327 Activity Against Multiple Bacterial Infections

- **Recce's Anti-Infective Research (AIR) Unit**

- Located within Murdoch Children's Research Institute, one of the **top three children's research institutes worldwide**
- Ongoing pre-clinical programs, **exploring new research development opportunities**

## Mycobacterium abscessus Data

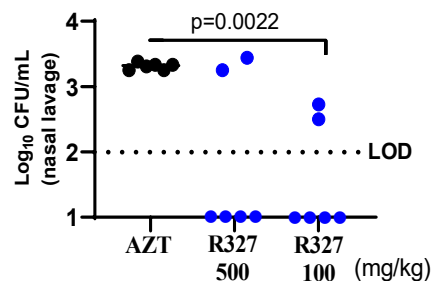


Human stem cell-derived macrophages (SCDM) infected with *M. abscessus* (Mabs) were treated with R327 or clarithromycin (CLA):

- **R327 demonstrated very good activity** against intracellular *M. abscessus* within human macrophages
- **No toxicity** against human SCDM was detected

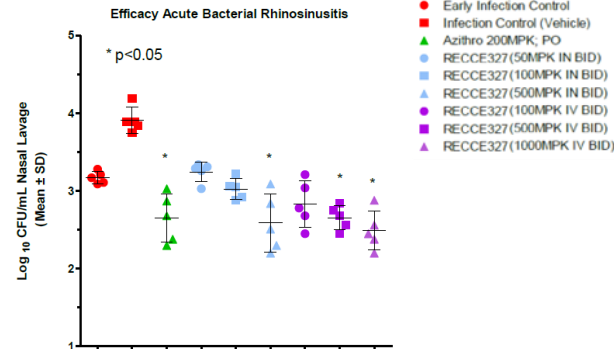
## Bacterial Sinusitis Data

### Study 2: *S. pneumoniae* colonisation



Mice infected with *S. pneumoniae* (clinical isolate ATCC 49619) were treated nasally, twice daily for 5 days, with R327:

- **Treatment of non-anaesthetised mice with R327 significantly reduced nasal infection** by *S. pneumoniae* compared to azithromycin control.
- **Eradicated infection in 8 out of 12 treated mice**



Nasal cavities of mice infected with *S. pneumoniae* (clinical isolate ATCC 49619)

- **Treatment of anaesthetised mice with R327** by both intranasal and intravenous routes **significantly reduced nasal infection** by *S. pneumoniae*

Separate study conducted by independent CRO

# Phase I Human Clinical Trial - Complete

- Study to assess IV infusion of RECCE<sup>®</sup> 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.
- In concurrence with the Therapeutic Goods Administration clinical trial regulatory procedures, the recruitment for the study is closed and marked 'Complete' with no 'Serious Adverse Events' reported.
- Safe up to and including 6,000mg using a 1-hour infusion
  - 60 subjects received R327, 20 subjects received placebo
- Plasma concentrations are linear vs. dose and "predictable"

120x dose amount\* — 6,000 mg ✓

80x dose amount\* — 4,000 mg ✓

60x dose amount\* — 3,000 mg ✓

40x dose amount\* — 2,000 mg ✓

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

# RECCE® 327 - Intravenous formulation – Phase I



## Summary of Results – All Primary Endpoints Achieved

- ✓ No serious adverse events (SAEs) or deaths were reported in this study.
- ✓ No clinically significant changes were noted in any hematology parameter(s) in any cohort during the course of the study.
- ✓ No clinically significant changes were noted in any chemistry parameter(s) in any cohort during the course of the study (Kidney and Liver functions all normal – no change in parameters).
- ✓ All coagulation parameters remained within normal limits or were deemed not clinically significant (Normal blood clotting properties were maintained).
- ✓ No clinically significant changes were noted in any urinalysis parameter(s) in any cohort during the course of the study (i.e. no adverse event/side effect).
- ✓ No clinically significant changes were noted in any vital sign (included systolic blood pressure, diastolic blood pressure, heart rate, respiratory rate, and body temperature) parameter(s) in any cohort during the course of the study.
- ✓ No clinically significant changes were noted in any 12-lead ECG parameter(s) in any subject in any cohort during the course of the study (no cardiac event).
- ✓ No clinically significant changes were noted in any cardiac telemetry parameter(s) in any subject in any cohort during the course of the study (no cardiac abnormalities during continuous heart monitoring whilst under observation).

# Phase I/II UTI/Urosepsis Rapid Infusion Clinical Trial - Complete

R327 has achieved multiple 'fast infusion' time stamps in line with intended future regulatory submissions

- Assessing R327 at faster administration rates (<1 hour)
- Trial aimed at positioning **R327 as first patient presentation** 'fast-infusion' **designed to stop any bacterial infection** in its tracks in any medical setting
- **Male and female subjects dosed**
- Results from this trial will pave the way for **R327 as a potential first-line treatment for patients suffering from UTI/Urosepsis**
- **Qualified Infectious Disease Product designation**
  - Awarded by the US FDA in 2017 for R327 bacteraemia (broad-spectrum bacterial sepsis).

*15 minutes*

*20 minutes*

*30 minutes*

*45 minutes*

*1 hour*



*UTI's are responsible for about 30% of all sepsis infections, defined as 'Urosepsis'*

# Topical Clinical Programs

## Phase I/II Clinical Trial – Treatment of Burn Wound Infections

- **Stage 1 Complete**
- Patients treated with R327 showed **good indications of safety and tolerability**
- **No serious adverse events** reported among patients
- Clinical investigators are preparing a new protocol of next stage
- **Stage 2 clinical trial** expected to be a randomised ‘head-to-head’ in patients with infected burn wounds, where R327G treatment is compared to existing treatment standard of care

## Phase I/II Clinical Trial – Diabetic Foot Infections

- **Interim data results released – achieving primary endpoints**
- Patients supported by in-home (out-patient) nurses trained in R327 treatment protocols
- Appointment of leading out-patient nursing group sees broadening of DFI patient trial population – increased probability of dosing completion
- Study across South Western Sydney health district – one of the highest prevalence rates of diabetes in NSW
- **Largest DFI study underway in Australia at this time**



*For illustrative purposes only – not final product*

# Phase I/II DFI Clinical Trial – Achieving Primary Endpoints

- Patients recruited had **mild skin and soft tissue DFI** including **multidrug-resistant Gram-positive and Gram-negative pathogens**
- **Study met all primary end points**
- **R327 well-tolerated in all patients; DFI's resolved/cured**
- Additional clinical sites to be launched in Australia and additional clinical trials will be launched internationally, in diabetic foot infections

| Summary of patients results | Application Frequency | Age (yrs)/Sex | Wound Location               | Pathogen Identified                               | Clinical Response                                     |
|-----------------------------|-----------------------|---------------|------------------------------|---|---|
| Patient 1                   | Daily                 | 32/M          | Left forefoot lateral aspect | Methicillin-Resistant <i>S. aureus</i>            | Escalated therapy*                                    |
| Patient 2                   | Second Daily          | 55/M          | Right hallux plantar aspect  | <i>S. aureus</i> , mixed skin flora and coliforms | Infection resolved/cured                              |
| Patient 3                   | Second Daily          | 51/M          | Left forefoot plantar aspect | <i>S. aureus</i> , mixed skin flora and coliforms | Infection resolved/cured                              |
| Patient 4                   | Daily                 | 70/M          | Left forefoot plantar aspect | Mixed skin flora                                  | Infection resolved/cured (in half the treatment time) |
| Patient 5                   | Daily                 | 64/M          | Right hallux dorsal aspect   | Mixed skin flora and coliforms                    | Infection resolved/cured                              |

\*Patient was on systemic therapy prior to commencing R327 treatment. Patient suffered from several comorbidities and escalated to systemic therapy.

# Phase II ABSSSI Clinical Trial – Ethics Approval Received

## Clinical trial overview

- **Human Research Ethics Committee approval received for Phase II clinical trial of R327 topical gel for testing against Acute Bacterial Skin and Skin Structure Infections (ABSSSI)**
  - Including Diabetic Foot and Wound infections across large unmet medical needs
- The Phase II clinical trial is an Open-label, Efficacy Study and Exploratory Evaluation of the Systemic Bioavailability of Single and/or Multiple Doses of R327 Topical Gel Applied to ABSSSI.
- The study aims to **provide critical data on the gel's effectiveness** in treating a broad range of ABSSSI indications.
- Study to be conducted by **Barwon Health** - one of the **largest** and **most comprehensive regional health services** in Australia, alongside other existing leading healthcare providers
- The **Global ABSSSI treatment market size was valued at \$7.3B USD in 2018** and is **projected to reach \$26B USD by 2032**, representing a CAGR of 9.5% between 2019 and 2032



# Strategic Partnership to Accelerate Clinical Program

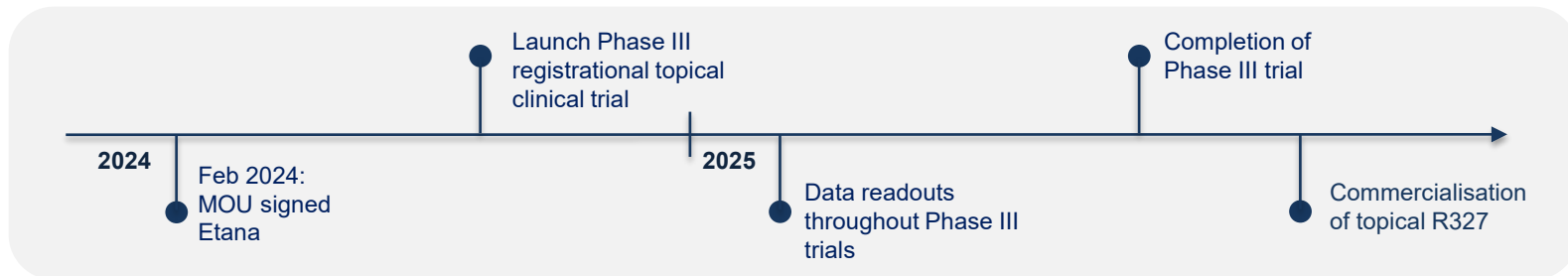
## Opportunity for accelerated path to market with registrational Phase III trial in South-East Asia

- **Opportunity** presents an innovative path to commercialisation
- **Memorandum of Understanding (MoU)** with leading Indonesian biomedical company PT Etana Biotechnologies (**Etana**)
- MoU aims to **facilitate late-stage clinical trials** in Indonesia, supporting the Indonesian Government's access to novel infectious disease medicines
- **Opportunity to access 10 ASEAN member states** covering a population of 670 million inhabitants
- **Patient populations readily available** to focus on significant unmet medical needs particular to the region
- **Significant bilateral initiative** supported by Australian and Indonesian Governments

**Indonesian Minister of Health, Mr. Budi Sadikin stated,**

*"The global health challenge of antimicrobial resistance is a pressing issue on the world stage. Indonesia welcomes collaborative initiatives and supports efforts to combat antimicrobial resistance, including the development of innovative therapeutics for infectious diseases."*

### Accelerated path to commercialisation\*



\*timeline is indicative only and subject to change



# Manufacturing & Scalability

## 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** produced per automated run
- This in-house pilot facility provides **clear benefits in cost and scalability** that will be instrumental to meet clinical testing demands as the technology pipeline continues towards commercialisation.
- Demonstrated **capability to support present and future human clinical trials.**

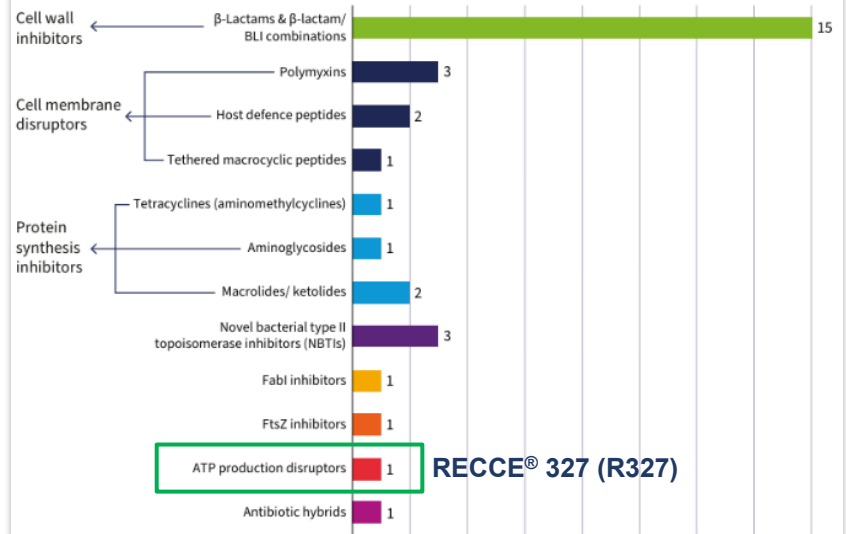


# RECCE® 327 – Global Recognition

## R327 added to World Health Organization's List of Antibacterial Products in Clinical Development

- Global recognition by the **World Health Organization (WHO)** – inclusion underscores significance of R327 in combating antimicrobial resistance.
- **Unique Mechanism of Action** – R327 uniquely classified as an adenosine triphosphate (ATP) production disruptor, the **only compound under this category.**
- **R327 recognised as a novel treatment** for a broad range of life-threatening and resistant bacteria.
- The report covers traditional and non-traditional antibacterial agents in development worldwide and evaluates to what extent the present pipeline addresses infections caused by priority pathogens.

Fig. 10. Distribution of traditional agents according to their antibiotic class



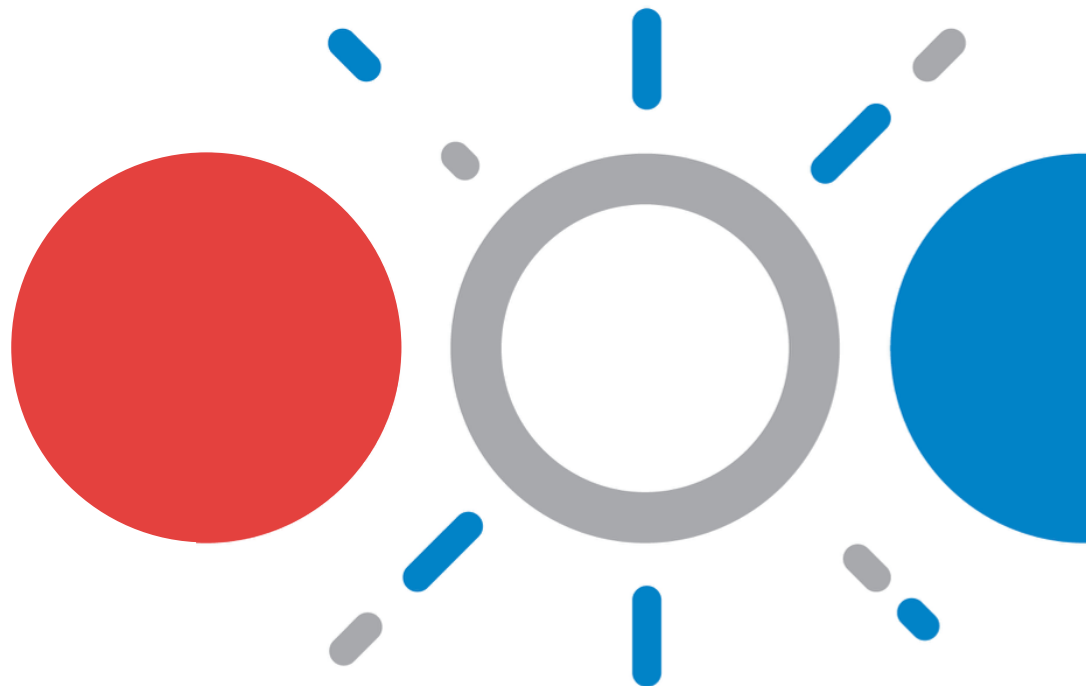
# Multiple Clinical Milestones – Achieved and Upcoming

## Significant milestones anticipated in H2 CY24

|  |                                      |
|--|--------------------------------------|
| <b>Phase I Safety Clinical Trial – Intravenous</b> <ul style="list-style-type: none"><li><i>Safety and Tolerability of R327 in Healthy Human Subjects</i></li></ul>  | <b>Complete</b>                      |
| <b>Phase I/II UTI/Urosepsis Rapid Infusion Clinical Trial – Intravenous</b> <ul style="list-style-type: none"><li><i>Trial demonstrated efficacy of R327 on bacterial growth in participants</i></li></ul>   | <b>Complete</b>                      |
| <b>Phase II – Acute Bacterial Skin and Soft Tissue Infection (ABSSSI)</b> <ul style="list-style-type: none"><li><i>Clinical trial approved to commence – Announced</i></li><li><i>Includes Diabetic Foot Infections</i></li><li><i>Interim data read outs throughout</i></li></ul> | <b>Ongoing – next update Q3 CY24</b> |
| <b>Phase II – UTI/Urosepsis Clinical Trial</b> <ul style="list-style-type: none"><li><i>First patient dosed</i></li></ul>  | <b>Q3 CY24</b>                       |
| <b>Phase III Registrational Clinical Trial</b> <ul style="list-style-type: none"><li><i>International expansion in Indonesia for DFI clinical trial</i></li></ul>  | <b>Q3 CY24</b>                       |
| <b>Commencement of US Department of Defence Burn Wounds Program</b> <ul style="list-style-type: none"><li><i>Non-dilutive capital to be received in the amount of USD \$2.0 million (AUD \$3.0 million)</i></li></ul>  | <b>Q3 CY24</b>                       |

# Appendix A

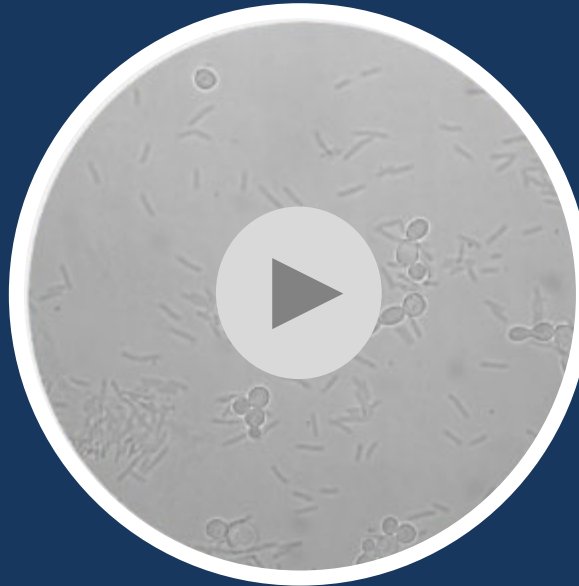
Supplementary Information on R327



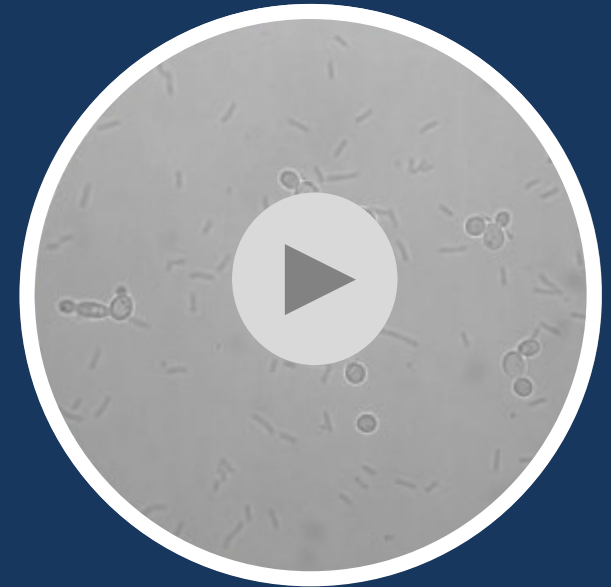
# RECCE<sup>®</sup> 327 Activity Against *Escherichia coli*

- *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)*



eukaryotic cells



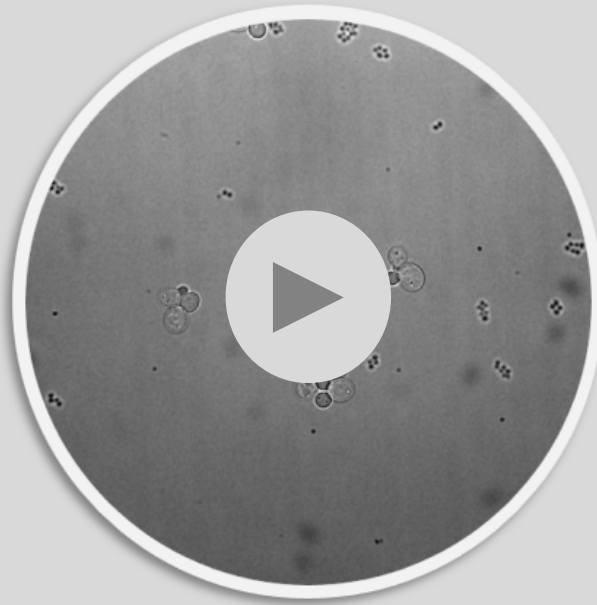
*E. coli*



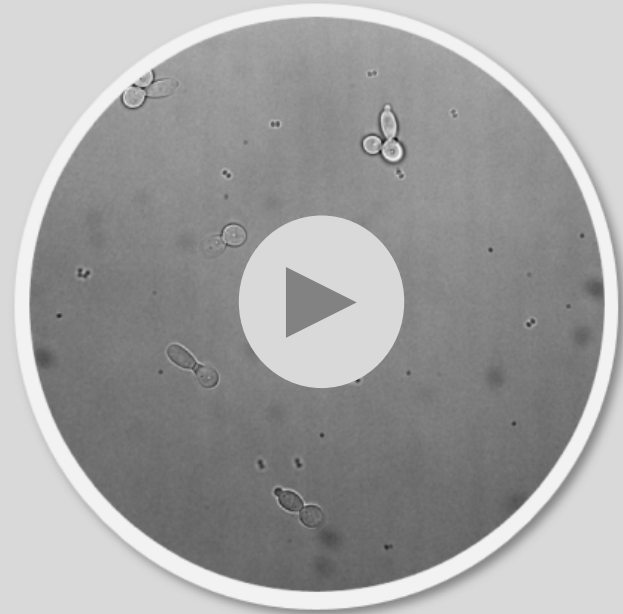
# RECCE<sup>®</sup> 327 Activity Against *Staphylococcus aureus*

- *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

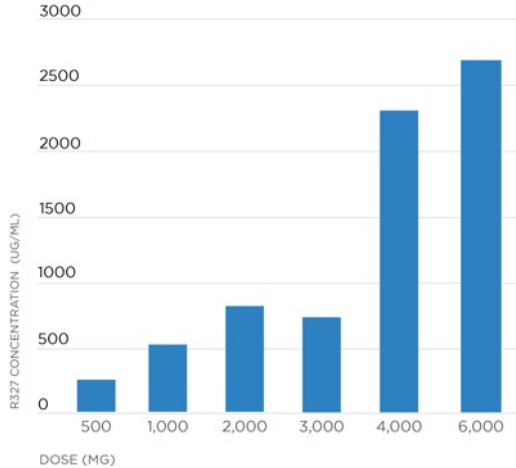


*S. aureus*

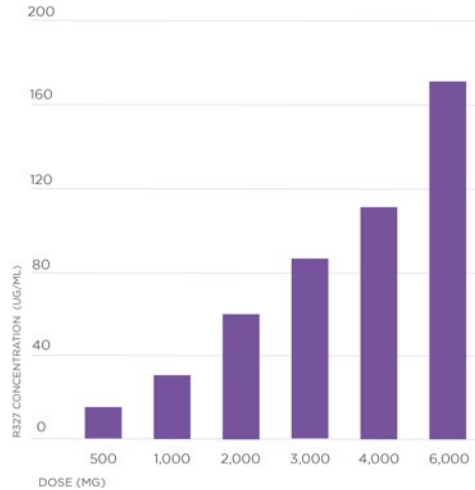
# RECCE® 327 Concentrates Safely in the Urine

NOT FOR RELEASE TO US WIRE SERVICES OR DISTRIBUTION IN THE UNITED STATES

Concentration of R327  
HUMAN URINE



Concentration of R327  
HUMAN PLASMA



Concentration of R327 in Urine Compared to Plasma

In over 60 healthy subjects

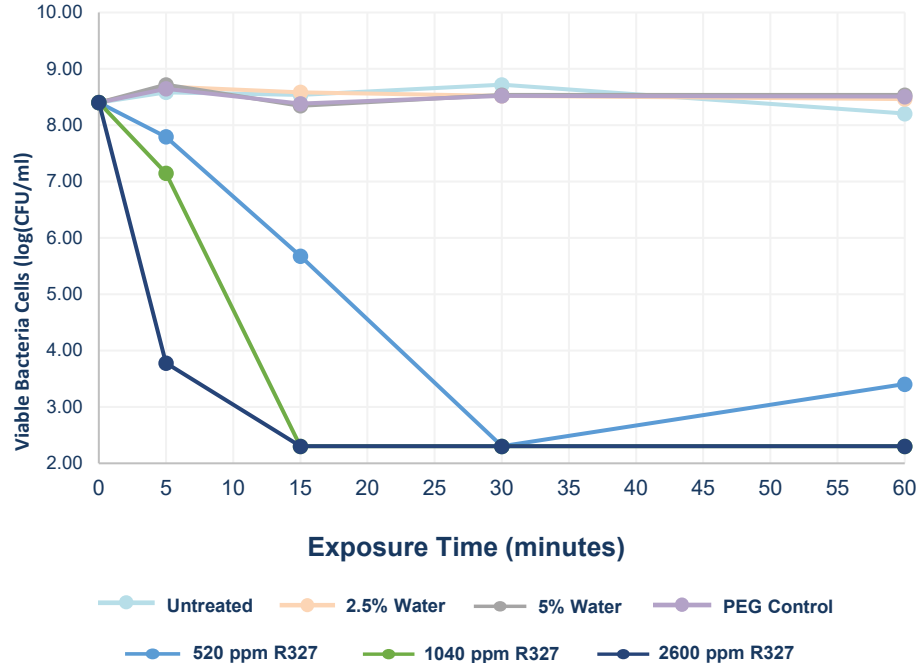
| Ratio Urine/Plasma - |
|----------------------|
| 16x                  |
| 17x                  |
| 14x                  |
| 9x                   |
| 21x                  |
| 16x                  |

- 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 Treated with RECCE® 327 in Urine



- 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 revived post-treatment
- 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

\*<https://halosil.com/what-are-logs-and-why-do-they-matter-in-preventing-infections/>



# Patient Case Study: TGA Special Access Scheme Category A

Day 0



Day 0 – Recce treatment  
Pre-treatment infection

Day 0



Day 0 – Recce treatment  
First Recce gel applied

Day 0



Day 0 – Recce treatment  
Gel application complete

Day 1



Day 1 – Recce treatment  
Post treatment

Day 30



Day 30 – Recce treatment  
Post treatment

- Patient Y **unresponsive to 4 x daily Cephalexin for 10 days**
  - Infection spreading and hospital ready.
- With only **one dosing application**, after 24 hours the **infection had clinically** responded – redness and swelling reduced

- No pre-treatment wound debridement.
- No stinging at any point reported.
- **R327 Gel worked quickly and effectively**

# Patient Case Study – TGA Special Access Scheme Category A

**Pre-Treatment**



Day 0 – Recce treatment  
**Significant bacterial infection**

**Day 7**



Day 7 – Recce treatment  
Initial redness and swelling  
minimising, wound drying up

**Day 10**



Day 10 – Recce treatment  
No signs of infection, no signs of pus  
formation, wound clearing up

**Day 14**



Day 14 – Recce treatment  
Wound improved, well tolerated

# Patient Case Study – TGA Special Access Scheme Category A

**Pre-treatment**



**Day 0 – Pre-treatment wound swab**  
**Growing culture of Gram-positive and Gram-negative bacilli**

**Day 1**



**Day 7 – Recce treatment**  
**Initial redness and swelling of the wound had minimised and found to be drying up.**

**Day 14**



**Day 14 – Recce treatment**  
**No signs of bacterial growth surrounding the wound**

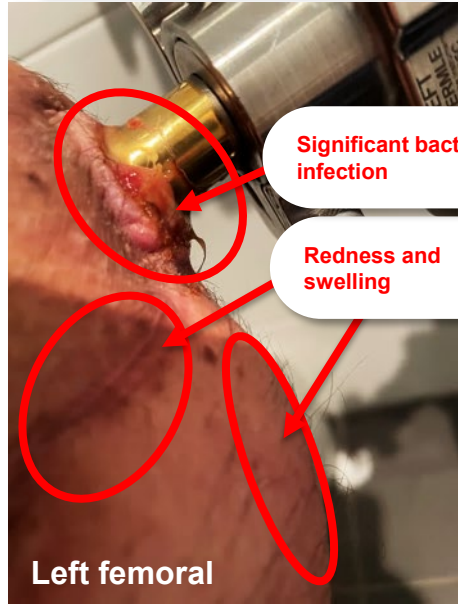
**Day 21**



**Day 21 – Recce treatment**  
**Wound had successfully healed, closed and dried up, with no signs of bacterial infection. R327G treatment well tolerated**

# Patient Case Study – TGA Special Access Scheme Category A

## Pre-Treatment



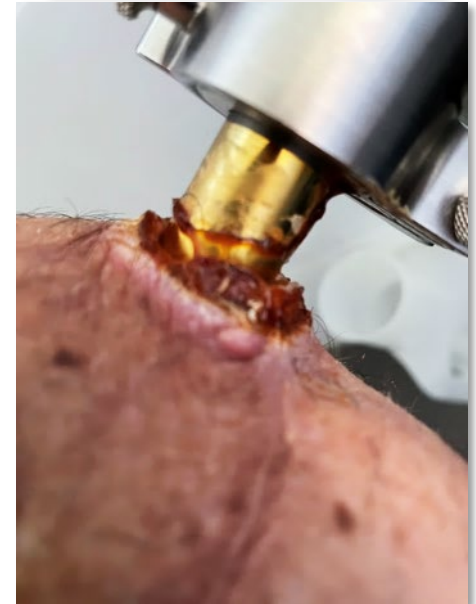
**Day 0 – Pre-treatment**  
Significant bacterial infection, redness and swelling around the implant (upper left thigh)

## Day 3



**Day 3 – Recce treatment**  
Initial redness and swelling minimising, wound healing and drying up

## Day 7



**Day 7 – Recce treatment**  
Wound was dried up and had improved with no signs of redness or swelling. R327G was applied daily and was well-tolerated.



# Patient Case Study – TGA Special Access Scheme Category A

**Pre-Treatment**



**Day 1 – Pre-treatment**  
**Osteomyelitis (serious infection of the bone), signs of initial biofilm formation, not responding to antibiotics**

**Day 3**



**Day 3 – Recce treatment**  
**Wound drying up with infection clearing, toe responding to R327G treatment**

**Day 7**



**Day 7 – Recce treatment**  
**Wound completely dried up, no signs of biofilm surrounding toenail, swelling significantly reduced**

# Patient Case Study – Special Access Scheme Category A

**Pre-Treatment**



**Significant bacterial infection**

**Day 0 – Pre-treatment**

**Significant bacterial infection – septic ankle arthritis, peri-prosthetic joint infection, osteomyelitis, *E. coli* refractory to multiple debridement and multiple antibiotics**

**Day 5**

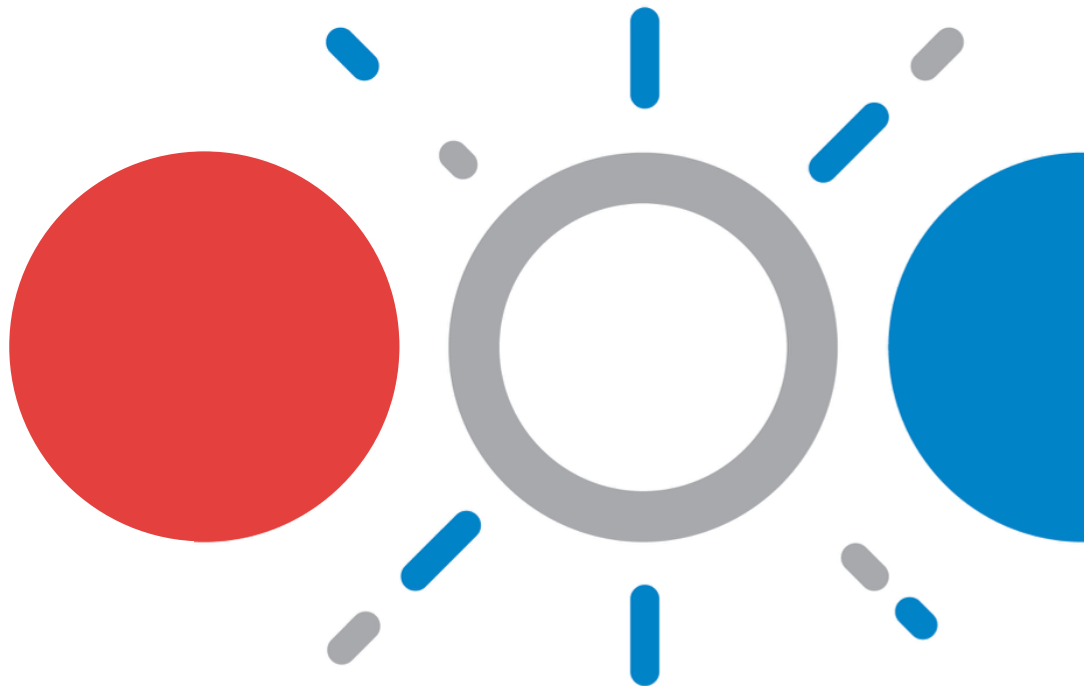


**Day 5 – Recce treatment**

**The discharge has cleared, and with no signs of edema present. R327G was applied once and was well-tolerated.**

# Appendix B

## International Selling Restrictions



# International Selling Restrictions

This document does not constitute an offer of new ordinary shares (**New Shares**) of the Company in any jurisdiction in which it would be unlawful. In particular, this document may not be distributed to any person, and the New Shares may not be offered or sold, in any country outside Australia except to the extent permitted below.

## HONG KONG

**WARNING:** This document has not been, and will not be, registered as a prospectus under the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32) of Hong Kong, nor has it been authorised by the Securities and Futures Commission in Hong Kong pursuant to the Securities and Futures Ordinance (Cap. 571) of the Laws of Hong Kong (the **SFO**). No action has been taken in Hong Kong to authorise or register this document or to permit the distribution of this document or any documents issued in connection with it. Accordingly, the New Shares have not been and will not be offered or sold in Hong Kong other than to “professional investors” (as defined in the SFO and any rules made under that ordinance).

No advertisement, invitation or document relating to the New Shares has been or will be issued, or has been or will be in the possession of any person for the purpose of issue, in Hong Kong or elsewhere that is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to New Shares that are or are intended to be disposed of only to persons outside Hong Kong or only to professional investors. No person allotted New Shares may sell, such securities in circumstances that amount to an offer to the public in Hong Kong within six months following the date of issue of such securities.

The contents of this document have not been reviewed by any Hong Kong regulatory authority. You are advised to exercise caution in relation to the Offer. If you are in doubt about any contents of this document, you should obtain independent professional advice.

## NEW ZEALAND

This document has not been registered, filed with or approved by any New Zealand regulatory authority under the Financial Markets Conduct Act 2013 (the FMC Act). The New Shares are not being offered or sold in New Zealand (or allotted with a view to being offered for sale in New Zealand) other than to a person who:

- is an investment business within the meaning of clause 37 of Schedule 1 of the FMC Act;
- meets the investment activity criteria specified in clause 38 of Schedule 1 of the FMC Act;
- is large within the meaning of clause 39 of Schedule 1 of the FMC Act;
- is a government agency within the meaning of clause 40 of Schedule 1 of the FMC Act; or
- is an eligible investor within the meaning of clause 41 of Schedule 1 of the FMC Act.

## SINGAPORE

This document and any other material relating to the New Shares have not been, and will not be, lodged or registered as a prospectus in Singapore with the Monetary Authority of Singapore. Accordingly, this document and any other document or materials in connection with the offer of sale, or invitation for subscription or purchase, of New Shares, may not be issued, circulated or distributed, nor may the New Shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore except pursuant to and in accordance with exemptions in Subdivision (4) Division 1, Part XIII of the Securities and Futures Act, Chapter 289 of Singapore (the “SFA”), or as otherwise pursuant to, and in accordance with the conditions of any other applicable provisions of the SFA.

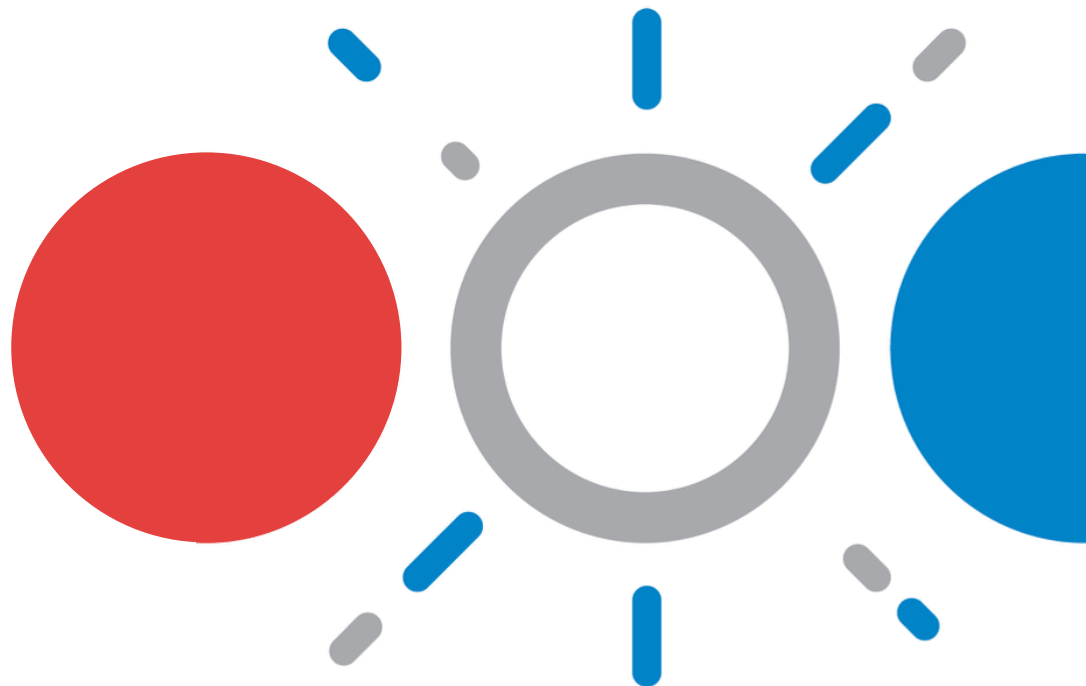
This document has been given to you on the basis that you are (i) an “institutional investor” (as defined in the SFA) or (ii) an “accredited investor” (as defined in the SFA). If you are not an investor falling within one of these categories, please return this document immediately. You may not forward or circulate this document to any other person in Singapore.

Any offer is not made to you with a view to the New Shares being subsequently offered for sale to any other party. There are on-sale restrictions in Singapore that may be applicable to investors who acquire New Shares. As such, investors are advised to acquaint themselves with the SFA provisions relating to resale restrictions in Singapore and comply accordingly.



# Appendix C

## Key Risks



# Key Risks

**This section discusses some of the key risks relating to an investment in Recce, which may have an impact on Recce's business, its financial and operational performance, and the value of Recce shares (including shares issued in connection with the Offer). Before investing in Recce, you should be aware that an investment in Recce has a number of risks, some of which are specific to Recce and some of which relate to listed securities generally, many of which are beyond the control of Recce. You should have regard to the relevant risks when considering the suitability of the investment for you.**

**You should consider publicly available information on Recce (such as that available on the websites of Recce and the ASX), carefully consider your personal circumstances and consult your stockbroker, accountant, solicitor or other professional adviser before investing in Recce shares. Nothing in this presentation is personal financial product advice and this document has been prepared without taking into account your investment objectives or personal circumstances.**

**The risks set out on the following pages are not intended to be in order of importance and you should read all of this Key Risks section in its entirety. The following is not an exhaustive list of all relevant risks involved with an investment in Recce. Please also note that there can be no guarantee that Recce will achieve its stated objectives or that any forward looking statements or forecasts contained in this presentation will be realised.**

# Key Risks

## RESEARCH AND DEVELOPMENT

The Company can make no representation that any of its research into or development of its technologies or further development of the Company's antibiotics will be successful or that they will be developed into products that are commercially exploitable. There are many risks inherent in the development of pharmaceutical products, particularly where the products are in the early stages of development. Projects can be delayed or fail to demonstrate any benefit, or research may cease to be viable for a range of scientific and commercial reasons.

## CHANGES IN LAWS AND REGULATIONS

The operation of the Company's business in the pharmaceutical industry is governed by a variety of laws, regulations and guidelines. While to the knowledge of management, the Company is currently in compliance with all current laws, changes to laws and regulations due to matters beyond the control of the Company may cause adverse effects to its operations. The introduction of new legislation or amendments to existing legislation by governments, or the respective interpretation of the legal requirements in any of the legal jurisdictions which govern the Company's operations or contractual obligations, could impact adversely on the assets, operations and, ultimately, the financial position and financial performance of the Company and its Shares. In addition there is a risk that legal action may be taken against the Company in relation to commercial, legal, regulatory or other matters.

## FORWARD-LOOKING INFORMATION

The forward-looking statements, opinions and estimates provided in this document rely on various contingencies and assumptions. Various factors and risks, both known and unknown, many of which are outside the control of the Company, may impact upon the performance of the Company and cause actual performance to vary significantly from expected results. There can be no guarantee that the Company will achieve its stated objectives or that forward-looking statements or forecasts will provide to be accurate.

## PRODUCT LIABILITY AND UNINSURED RISKS

The Company is exposed to potential product liability risks which are inherent in the research and development, manufacturing and marketing and use of its technology or products developed. Whilst the Company has in place a level of insurance suitable for its current business undertakings, the

Company may not be able to maintain insurance for product or service liability on reasonable terms in the future and, in addition, the Company's insurance may not be sufficient to cover large claims, or the insurer could disclaim coverage on claims. Although the Company endeavours to work to rigorous standards there is still the potential for the technology or developed products to contain defects which may result in failures. These defects or problems could result in the loss of or delay in generating revenue, loss of market share, failure to achieve market acceptance, diversion of development resources, and injury to the Company's reputation or increased insurance costs.

## RISK OF DELAY AND CONTINUITY OF OPERATIONS

The Company may experience delays in achieving some or all of its milestones, including but not limited to product development, obtaining regulatory approvals, or delays in sales of licensing. The Company is also dependent on amongst other things its technology, key personnel and IT systems. Any disruption or delay to any key inputs could impact adversely on the Company.

## RESEARCH & DEVELOPMENT GRANT (COMMONWEALTH)

The Company is eligible each year for an R&D Tax Incentive refund. The R&D Tax Incentive is an Australian Government program under which companies receive cash refunds for 43.5% of eligible expenditure on research and development. There is no guarantee that this program will continue or that the eligibility criteria will not change. Refunds are subject to audit by the Australian Tax Office and AusIndustry which may result in a requirement for repayment in certain circumstances.

## INTELLECTUAL PROPERTY

The Company's ability to leverage its innovation and expertise depends upon its ability to protect its intellectual property and any improvements to it. The intellectual property may not be capable of being legally protected, it may be the subject of unauthorised disclosure or be unlawfully infringed, or the Company may incur substantial costs in asserting or defending its intellectual property rights. Any failure to protect the Company's intellectual property, unauthorised disclosure or unlawfully infringed could enable competitors to develop generic products or use its proprietary information to develop other products that compete with the Company's products or cause additional, material adverse effects upon the Company's business, results of operations and financial condition.

# Key Risks

## KEY PERSONNEL

The Company depends on the talent and experience of its personnel as its primary asset. There may be a negative impact on the Company if any of its key personnel leave. It may be difficult to replace them, or to do so in a timely manner or at comparable expense. Additionally, any key personnel of the Company who leave to work for a competitor may adversely impact the Company. In summary, the Company's ability to attract and retain personnel will have a direct impact on its ability to deliver its commercialisation and commitments. Additionally, increases in recruitment, wages and contractor costs may adversely impact upon the financial performance of the Company.

## COMPETITION

The pharmaceutical industry is intensely competitive, and the development of suitable antibiotics is very difficult and demanding; even more so if this competition is against parties who may have larger resources than the Company. As a result, there is the risk the Company may be beaten to the market by one or more competitors.

## DIVIDENDS

There are a range of factors that determine the payment of dividends on Shares. These include the profitability of the business, its cash reserves, future capital requirements and obligations under debt facilities. The Board will determine any future dividend levels based upon its operating results and financial standing at the time. There is no guarantee that any dividend will be paid by the Company.

## ADDITIONAL REQUIREMENTS FOR CAPITAL

The Company's capital requirements depend on numerous factors. Depending on the Company's ability to generate income from its operations, the Company may require further financing in addition to amounts raised under the Offer. Any additional equity financing will dilute shareholdings, and debt financing, if available, may involve restrictions on financing and operating activities. If the Company is unable to obtain additional financing as needed, it may be required to reduce the scope of its operations and may be prevented from progressing the commercialisation of its technology. There is however no guarantee that the Company will be able to secure any additional funding or be able to secure funding on terms favourable to the Company.

## GENERAL MARKET AND SHARE PRICE RISKS

There are general risks associated with any investment in the share market. The price of Shares may increase or decrease due to a number of factors. Those factors include fluctuations in domestic or global financial markets and general economic conditions, including interest rates, inflation rates, exchange rates, commodity and oil prices, changes to government fiscal, monetary or regulatory policies, legislation or regulation, the removal or inclusion of the Company from market indices, and the nature of markets in which the Company operates.

## TAX AND ACCOUNTING

Australian accounting standards and tax laws (including GST and stamp duty taxes), or the way they are interpreted, are subject to change from time to time, which may impact the Company's financial position or performance.

## FOREIGN EXCHANGE RATE FLUCTUATION

The expenditure of the Company is and will be in Australian and other various foreign currencies, including the US dollar. This exposes the Company to fluctuations in exchange rates, which is beyond the Company's control. This could adversely impact the profitability of the Company's foreign operations.

## LITIGATION

Legal proceedings and claims may arise from time to time in the ordinary course of the Company's business and may result in high legal costs, adverse monetary judgments and/or damage to the Company's reputation which could have an adverse impact on the Company's financial position or performance and the price of its shares.

## SPECULATIVE INVESTMENT

The above list of risk factors ought not to be taken as exhaustive of the risks faced by the Company or by investors in the Company. The above factors, and others not specifically 21 referred to above, may in the future materially affect the financial performance of the Company and the value of the securities offered under this Offer Booklet. Therefore, the Shares to be issued pursuant to this Offer Booklet carry no guarantee with respect to the payment of dividends, returns of capital or the market value of those securities. Potential investors should consider that an investment in the Company is speculative and should consult their professional advisers before deciding whether to apply for securities pursuant to this Offer Booklet.