

# An afternoon with ORDS

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## Biotech & MedTech Conference

ASX:RCE | FSE:R9Q

November 2024

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# Leading Anti-Infective Company with Commercial Launch

*Expected in 2026*

- Australian clinical-stage biotech company developing a new class of Synthetic Anti-Infectives
- **Upcoming Phase III initiation in Indonesia** of main lead asset RECCE® 327 Gel for potential **approval in 2026 for the treatment of Diabetic Foot Infection**
- **US FDA Qualified Infectious Disease Product designation** provides 10 years of market exclusivity plus fast-track approval\*
- 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**



# 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.

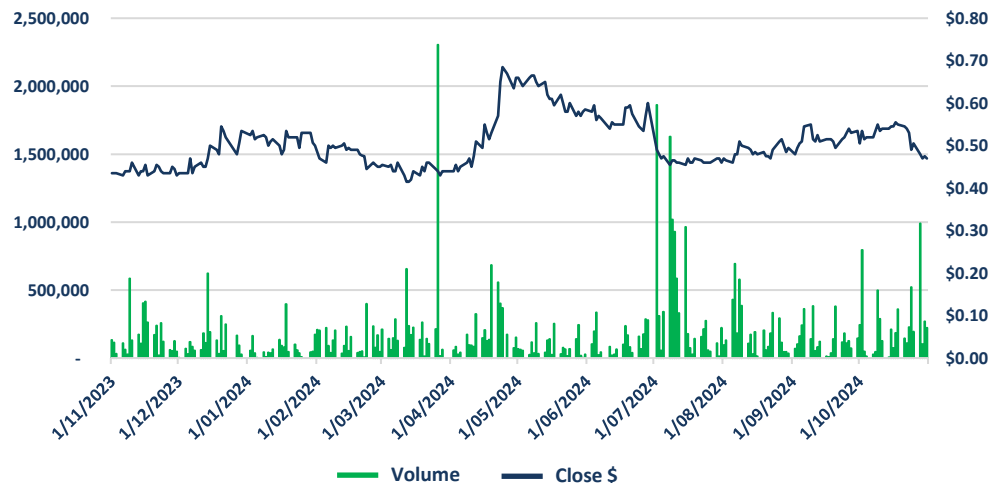
# Company Overview

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

## Capital Structure – November 2024

ASX & FSE Code	RCE, R9Q
Share Price	AUD \$0.4900
3-Month Average Volume	148.63k
Shares on Issue	231.87 million
Unlisted Options (Avg \$1.54)	13.9 million
Market Capitalisation	AUD \$106.661 million
Cash at Bank	AUD \$6.33 million*
Top 20 Shareholders	51%
Debt	Nil

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



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



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



**I.V. and topical treatments advancing** for UTI/Urosepsis and ABSSSI including DFI; as well as US Department of Defense Burn Wound Program and Indonesian clinical trials for topical treatments.



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

# 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**.

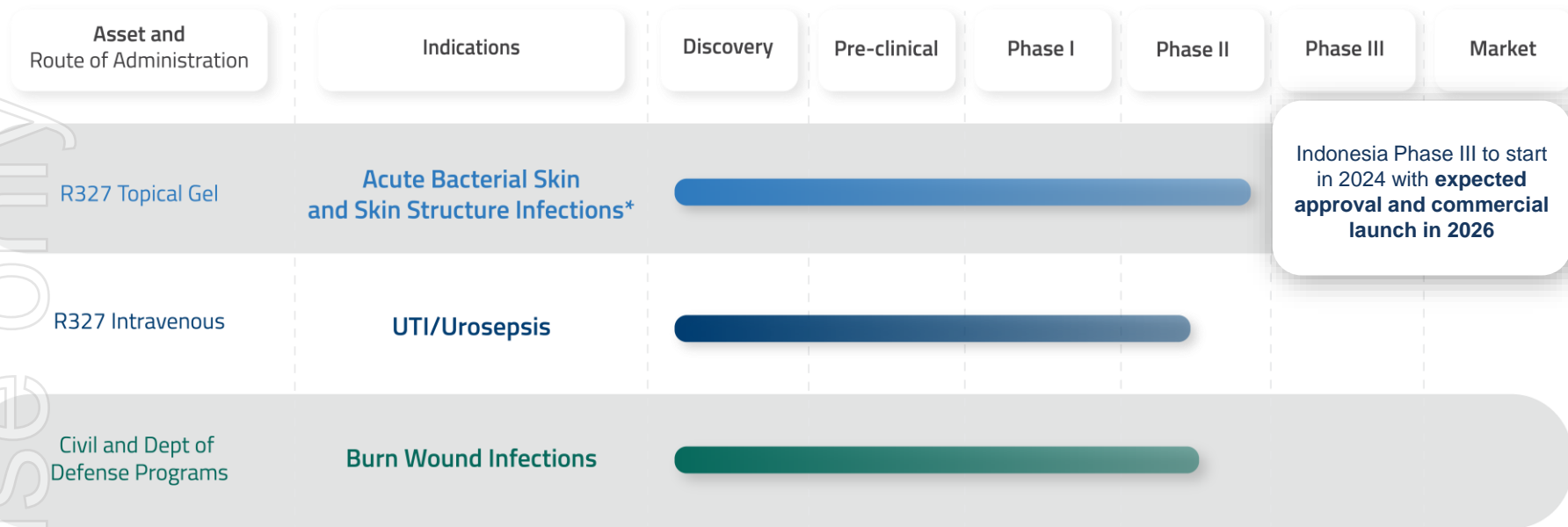


- **NO** pre-formed natural superbugs.
- Very broad-spectrum coverage of bacteria with **no signs of resistance**.
- **Universal Mechanism of Action** - does not succumb to resistance.
- **Broad Spectrum capability** and maintains its activity even with repeated use.
- **Extremely rapid onset of effect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



# A Diversified Pipeline

*Rapidly Evolving Towards Commercial Launch*



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

\*\* Completed pilot civil Phase II Burn Wound Infections Study; US\$2M grant for Department of Defense pre-clinical pipeline in progress



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

## By Leading Experts in Bacterial MoA Analysis

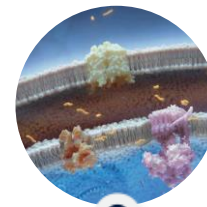
- Novel mechanism which targets rapid access to and shut down of bacterial energy production (ATP) **which results in bacterial death of both active and resting bacteria.**
- **Activity of R327 is measured in minutes** not hours like most other antibiotics.
- **Host cells not negatively impacted** by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

Stage 1



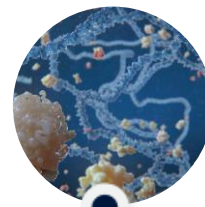
R327 arrests cell growth and permeabilizes cell membranes

Stage 2



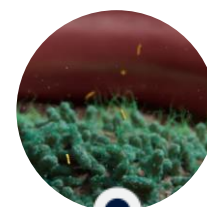
R327 disrupts bacterial cellular energetics, depleting ATP

Stage 3



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

Stage 4



R327 is rapidly and irreversibly bactericidal

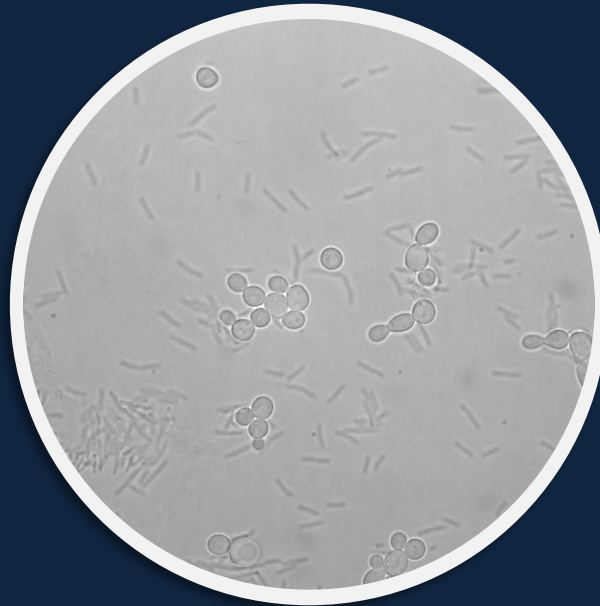




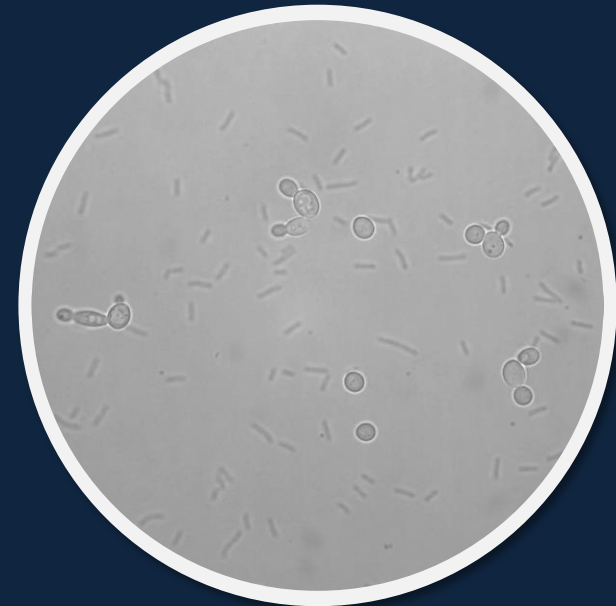
# RECCE<sup>®</sup> 327 Activity Against *Escherichia coli*

- *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*



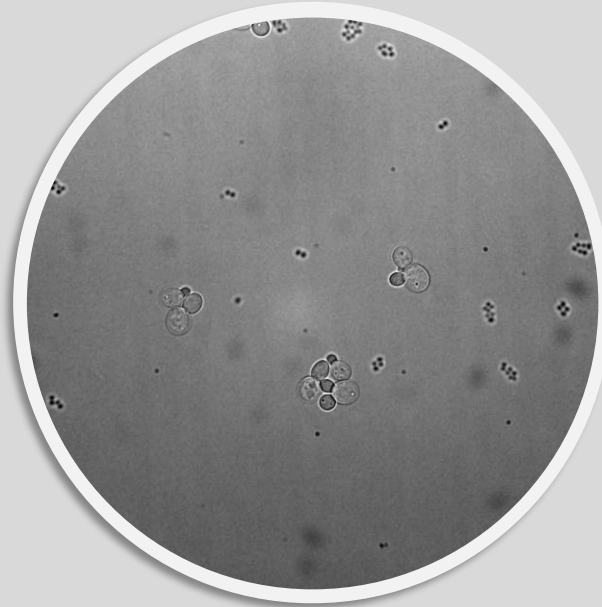
# RECCE<sup>®</sup> 327 Activity Against *Staphylococcus aureus*

- *S. aureus* bacterial growth slower than *E. coli*, not affecting eukaryotic cells.

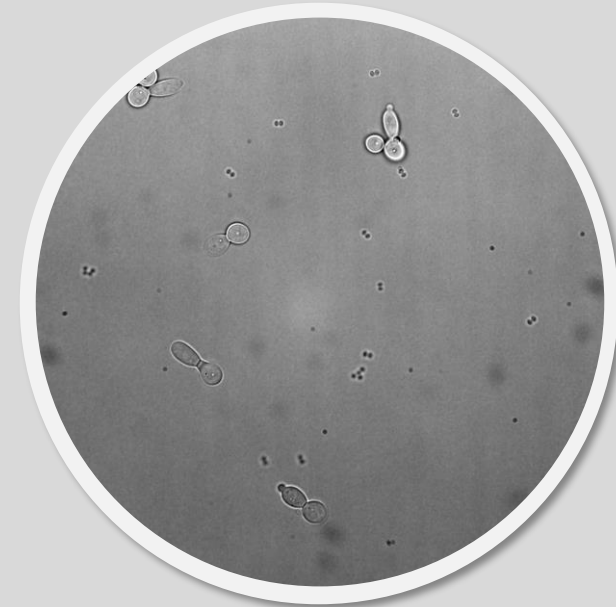
- **R327 at 2,300 ppm** shown to be highly effective against *S. aureus* without affecting growing, healthy eukaryotic cells.

- **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*

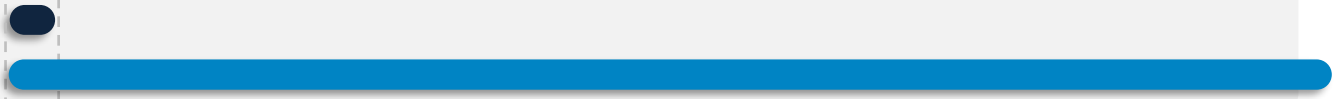
# RECCE<sup>®</sup> 327 Maintains Activity

Number of repeats before displaying loss of antibiotic activity

Bacteria\*

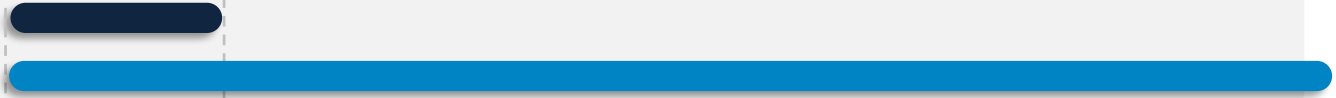
2 4 6 8 10 12 14 16 18 20 22 24 25 →

*Escherichia coli*

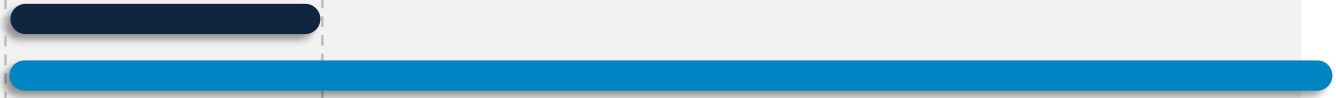


25 repeats at time of discovery was sufficient for PCT patent applications, with no sign of resistance.

*Pseudomonas aeruginosa*



*Staphylococcus aureus*



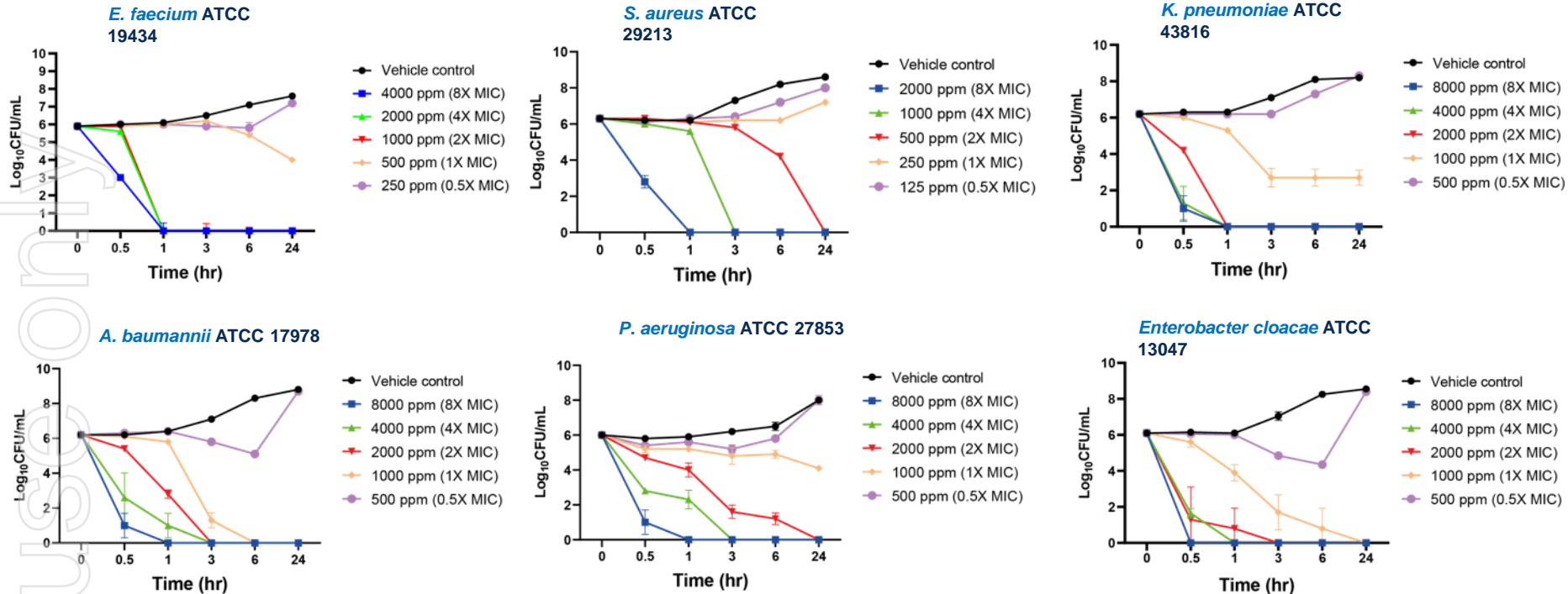
\*Antibiotic Sensitive Strains

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

● Amoxicillin

● RECCE<sup>®</sup> 327

# Bactericidal Effect of RECCE® 327 on ESKAPE Pathogens

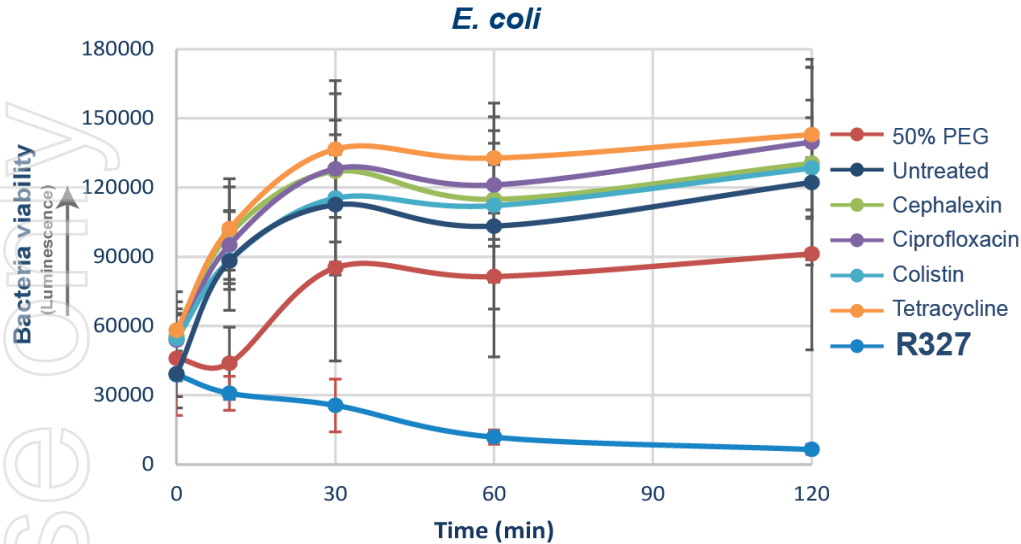


• Average time-kill curves of R327 at various concentrations against strains of ESKAPE pathogens (tested in duplicate)

• 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.

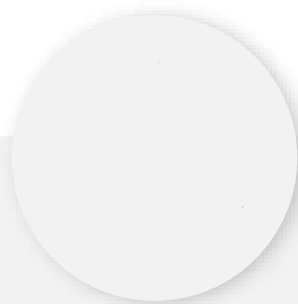
*“R327 kills bacteria in conditions where other antibiotics are ineffective.”*

*- 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).

# RECCE<sup>®</sup> 327 Summary Results – Phase I – Complete

*Double-blind, Placebo-controlled, Single Ascending-dose, Safety and Pharmacokinetic Study in Healthy Participants*



✓ Safe and well tolerated at doses up to 6,000mg given as a 1-hour intravenous infusion;

✓ No Serious Adverse Events;

– All AE's mild or moderate

✓ No significant changes in any laboratory test, EKG or telemetry;

✓ Concentrations of RECCE<sup>®</sup> 327 increased with dose,  $t_{1/2}$  increased with dose: 3-5 hours at higher doses

✓ Urine concentrations were up to 20 times higher than plasma concentrations



# Summary – Completed and Upcoming Clinical Trials

Successfully streamline and accelerate current clinical trial processes in chosen indications and routes of administration

## Completed Clinical Trials

### Phase I Clinical Trial *Intravenous*

- Complete 80 subject data safety review
- Data provided for safety and tolerability of R327

### Phase I/II UTI/Urosepsis Rapid Infusion Clinical Trial *Intravenous*

- Key findings: highest dose of 4,000mg of R327 I.V. over 30 minutes
- Consistent efficacy across participants, clear impact on bacterial growth build-up over time in urine, sustained effectiveness and rapid reduction in bacteria.

### Phase I/II Diabetic Foot Infection Clinical Trial *Topical Gel*

- All primary endpoints were met in this trial
- Achievement further solidifies R327's potential across multiple indications

## Upcoming Clinical Trial Milestones

### Phase II ABSSSI Clinical Trial *Topical Gel*

- 20 of 30 patients dosed - in final stages
- **All patients completing treatment with R327G had a positive primary endpoint** (achieving either complete cure or improvement)

**To be completed CY 2024**

### Phase III Registrational Clinical Trial in Indonesia *Topical Gel*

- Recce has significantly progressed regulatory submissions with the Indonesian Drug and Food Regulatory Authority and Human Ethics Committee
- Phase III trial will be focused on the treatment DFIs - expected to be approved imminently

**Regulatory approval imminent to commence  
Phase III clinical trial**



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

*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).

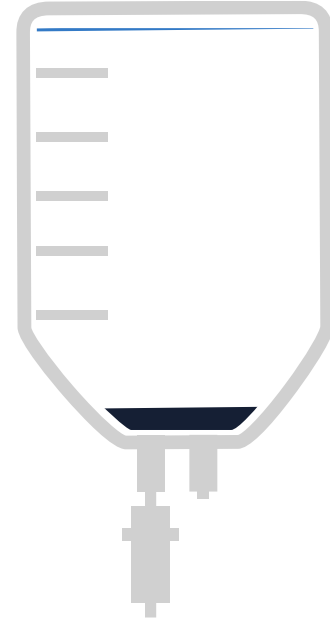
*15 minutes*

*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 Move into Phase III

## 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 (DFI)

- **Interim data results released – primary endpoints achieved**
- 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



For illustrative purposes only – not final product

**Phase III in Indonesia to start in late 2024**



# Phase I/II DFI Clinical Trial – Achieved 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**

## Summary of patients results

Application Frequency	Age (yrs)/Sex	Wound Location	Pathogen Identified	Clinical Response
Daily	32/M	Left forefoot lateral aspect	Methicillin-Resistant <i>S. aureus</i>	Escalated therapy*
Second Daily	55/M	Right hallux plantar aspect	<i>S. aureus</i> , mixed skin flora and coliforms	Infection resolved/cured
Second Daily	51/M	Left forefoot plantar aspect	<i>S. aureus</i> , mixed skin flora and coliforms	Infection resolved/cured
Daily	70/M	Left forefoot plantar aspect	Mixed skin flora	Infection resolved/cured (in half the treatment time)
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 – Dosing Halfway Complete

## Efficacy Data and Safety Approval Received

- Non-Data Safety Monitoring Board unanimously agree **R327G is safe and well-tolerated in patients** – demonstrating **highly encouraging efficacy results**
- All patients completing treatment with R327G had a **positive primary endpoint** - achieving either **complete cure or improvement**, seen as early as 7 days
- **No Serious Adverse Events** noted in patients - recommendation for clinical trial to continue
- **Wide variety of infecting bacteria** (Gram positive and Gram negative) were isolated and **successfully treated** with Improvement/Cure of infection in all patients that continued with their treatment.

Patient #	Age (yrs)/Gender	Infection	Clinical Response
Patient 1	88/M	ABSSSI	Cure (Day 7)
Patient 2	53/M	ABSSSI	Cure (Day 7)
Patient 3	49/M	ABSSSI	Cure (Day 7)
Patient 4	63/F	ABSSSI	Cure (Day 7)
Patient 5	46/M	ABSSSI	Cure (Day 14)
Patient 6	63/F	ABSSSI	Cure (Day 14)
Patient 7	67/M	ABSSSI	Improvement (Day 7)
Patient 8	72/M	ABSSSI	Improvement (Day 7)
Patient 9	70/M	ABSSSI	Improvement (Day 7)
Patient 10	59/M	ABSSSI	Improvement (Day 7)
Patient 11	63/M	ABSSSI	Improvement (Day 7)
Patient 12	68/M	ABSSSI	Improvement (Day 14)
Patient 13	81/F	ABSSSI	Withdrawn*
Patient 14	84/F	ABSSSI	Improvement (Day 14)

\*While no serious adverse events were noted, one patient was discontinued due to pain at the wound site which was judged to be unlikely related to R327G.

# 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 7**



**Day 10**



**Day 14**



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

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

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

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 7**



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**

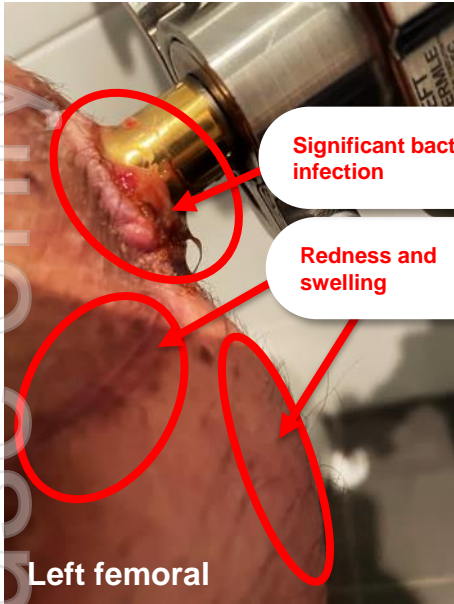


Day 21 – Recce treatment  
Wound had successfully healed, closed and dried up, with no signs of bacterial infection.  
R327G treatment well tolerated



# Patient Case Study – TGA Special Access Scheme Category A

## Pre-Treatment



Significant bacterial infection

Redness and swelling

Left femoral

Day 0 – Pre-treatment

Significant bacterial infection, redness and swelling around the implant (upper left thigh)

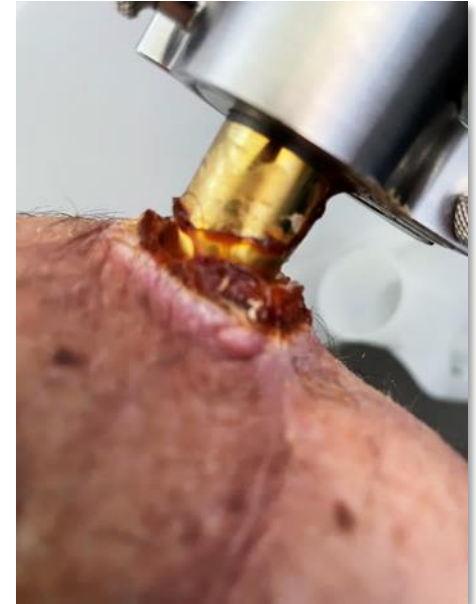
## Day 3



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**

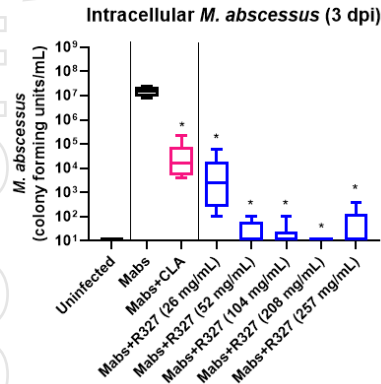
**The discharge has cleared, and with no signs of edema present. R327G was applied once and was well-tolerated.**

# RECCE<sup>®</sup> 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

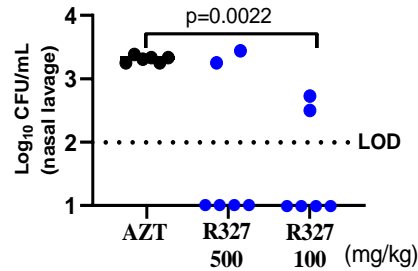


Human stem cell-derived macrophages (SCDM) infected with *M. abscessus* (Mabs) were treated with R327 or clarithromycin (CLA):

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

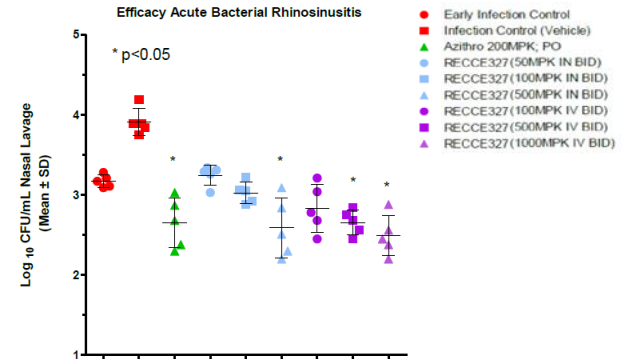
### Bacterial Sinusitis Data

#### 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

# Robust Worldwide Intellectual Property Portfolio

*Recce's patent portfolio contains 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

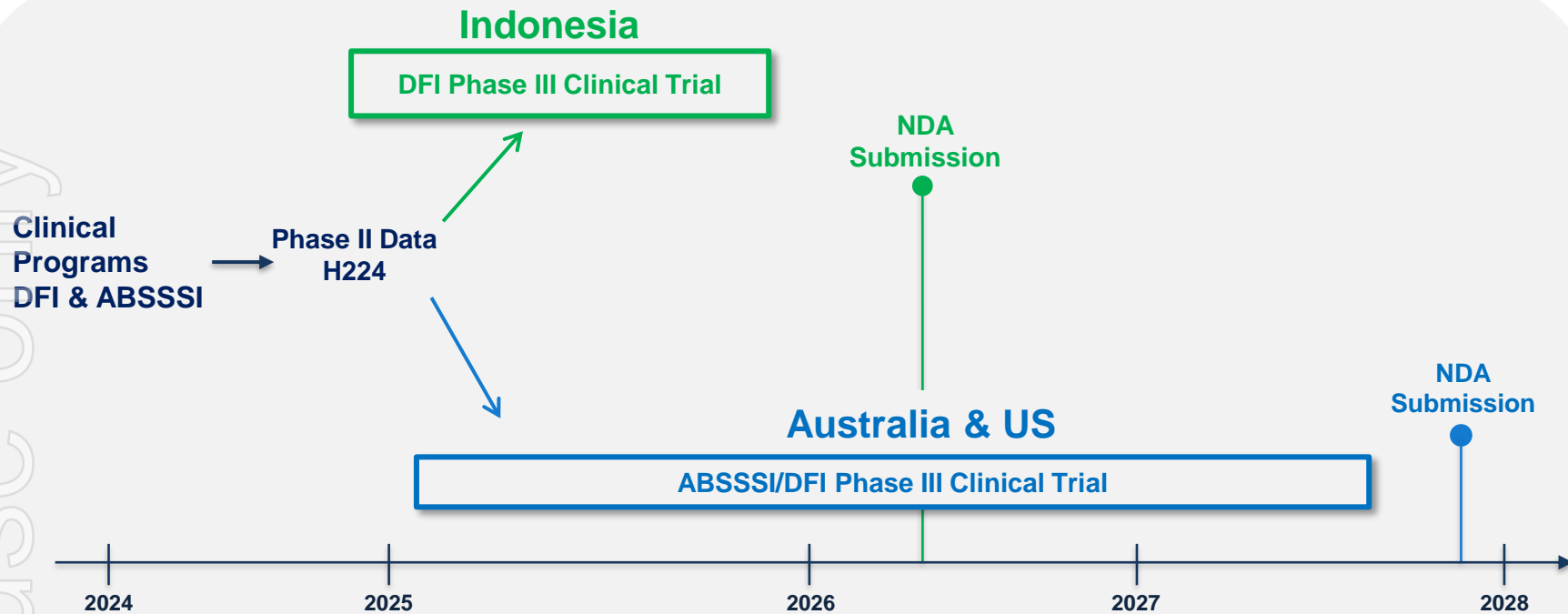
**Family 1** group relates to the Company's Unique and Highly Economical Manufacturing Process and use of the Polymer in Treatment of Diseases.

**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**

# Recce's Commercialisation Pathway



# 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 – completing **5,000 doses a week under GMP**
- 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.**



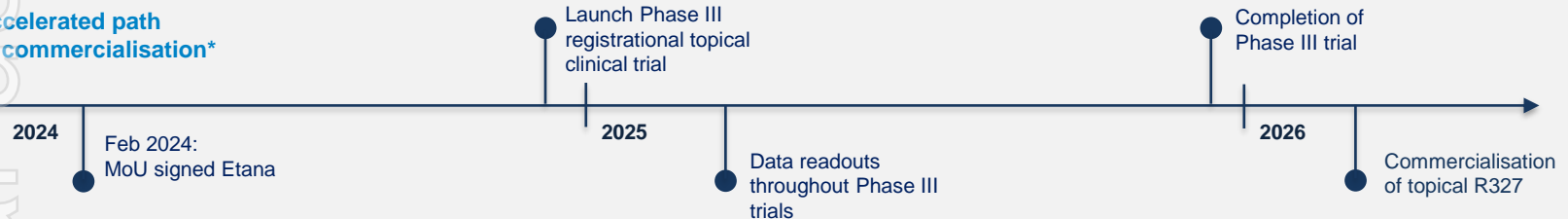
# Strategic Opportunity in South-East Asia to Accelerate Clinical Program

- **Memorandum of Understanding (MoU)** with leading Indonesian biomedical company PT Etana Biotechnologies, supporting the Indonesian Government's access to novel infectious disease medicines
- **Significantly progressed regulatory submissions** with the Indonesian Drug and Food Regulatory Authority, Badan POM and an independent Human Ethics Committee.
- Submissions seek **approval to begin a Registrational Phase III clinical trial in Indonesia**
- A successful outcome in this trial would represent a substantial advancement toward market authorisation
- **Opportunity to access 10 ASEAN member states** covering a population of 670 million inhabitants
- **Significant bilateral initiative** supported by Australian and Indonesian Governments



Recce & Badan POM Team's - Recce CEO James Graham (centre left) and Head of Drug and Food Authority Badan POM, Professor Taruna Ikrar (centre)

## Accelerated path to commercialisation\*



\*timeline is indicative only and subject to change

# Department of Defense R&D Efforts

- **Recce awarded funding** for FY23 Military Burn Research Program under the *U.S. Army Medical Research and Development Command*, via a Congressionally Directed Medical Research Program Award.
- **Proposal Title:** *A Novel, Synthetic Anti-infective Drug Candidate, R327, for the Acute Treatment of Burn Wounds and Downstream Sequelae*
- **US~\$2 Million final contract commenced Q3 2024**
- **Project specific aims include:**
  - Evaluate efficacy of a gel application of R327 to treat burn wound infections in a rat thermal wound infection model
  - Develop a suitable hydrogel dressing impregnated with R327 and evaluate efficacy to treat burn wound infections in a pig thermal wound infection model.

**Future expansion areas beyond this grant may include additional studies addressing biothreat indications.**



U.S. Army Medical Research and Materiel Command

## Other Recent Department of Defense Efforts:

- ✓ Presented to the Biomedical Advanced Research and Development Authority (BARDA)
- ✓ Presented at the 2024 MHSRS Symposium
- ✓ Submitted Public Comment to the members of US Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria



# Government/Private Enterprise Partnerships

*Funding, research partnerships, licensing, grant submissions, military areas of interest*

## Domestic Partnerships & Funding

### Awarded AusIndustry Advanced Overseas (R&D) Funding

- Recce awarded AUD \$54,947,284 across infectious disease portfolio for applicable R&D expenditure for its Synthetic Antibiotic and Anti-Viral R&D
- Largest awarded in Australian history 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

### Continued Collaboration with Murdoch Children's Research Institute (MCRI)

- Collaboration with MCRI remains a pivotal element of Recce's strategy
- Enables Recce to tap into ground-breaking research and clinical expertise to bolster pipeline

## Global Partnerships & Funding

### Memorandum of Understanding (MoU) with PT Etana Biotechnologies (Etana)

- Initiative supported by the Australian and Indonesian Governments
- Collaboration accelerates late-stage clinical programs and expands reach into the broader ASEAN market.

### US Department of Defense granted R327 Gel (R327G) as a topical treatment for Burn Wound Infections

- Grant funding of USD \$2 million (AUD \$3 million)
- R327G will be evaluated as a gel-impregnated wound dressing to treat burn wounds in active military scenarios

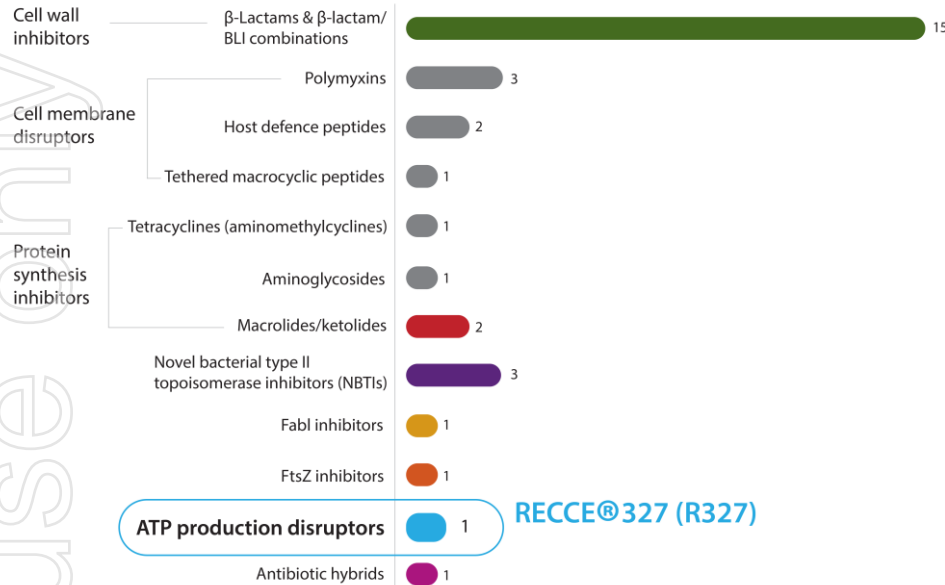




# RECCE<sup>®</sup> 327 – Global Recognition

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

Distribution of traditional agents according to their antibiotic class



- 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.




World Health Organization

# Summary – Significant Value Creating Opportunities

 *Phase II Acute Bacterial Skin and Skin Structure Infection **clinical trial to be clinically completed CY24***

 ***Indonesian Phase III registrational clinical trial data read-out and regulatory submission expected in late 2025, potential market approval and commercial launch in H1 2026***

 *Upon completion of Phase III registrational clinical trial, enables Recce to replicate regulatory approval for R327G across the broader ASEAN region*

 *Australia/NZ Phase III clinical trial of R327G expected to start in H1 2025*

 *Expansion of Recce's Global Regulatory Strategy including US IND and Department of Defense*

Internal use only



**Thank you**



**recce.com.au**