

An afternoon with ORDS

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.





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



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 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. **Pfizer**



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.



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





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.

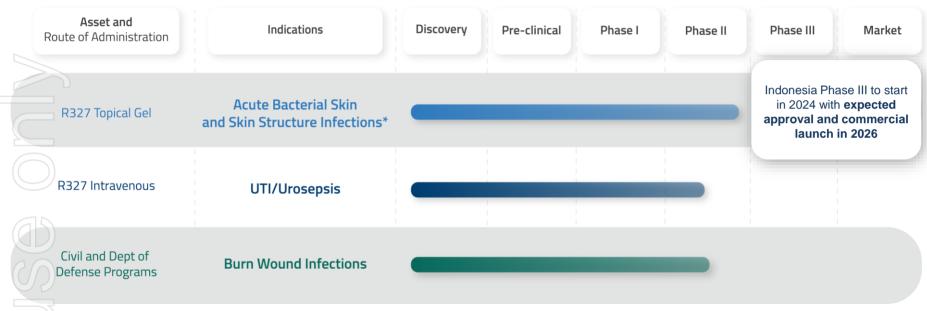


NO pre-formed natural superbugs.

- 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 MoA¹

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® 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



RECCE® 327 Activity Against Escherichia coli

 E. coli grows fast.
 Eukaryotic cells healthy and not affected.

- R327 at 3,000 ppm shown to be highly effective against
 E. coli without affecting growing, healthy eukaryotic cells.
- R327 rapidly and irreversibly shuts down the ATP in *E. coli*, not allowing it to divide and grow.









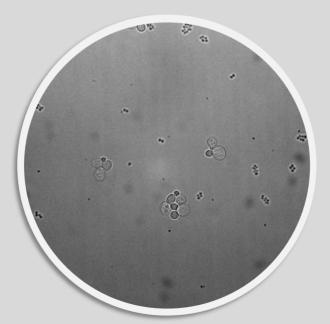
E. coli

RECCE® 327 Activity Against Staphylococcus aureus

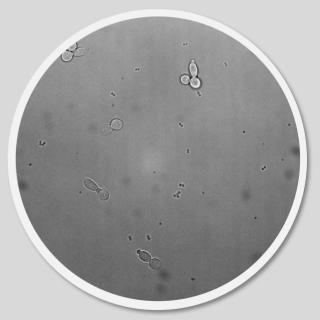
• *S. aureus* bacterial growth slower than *E. coli*, not affecting eukaryotic cells.

- R327 at 2,300 ppm 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)





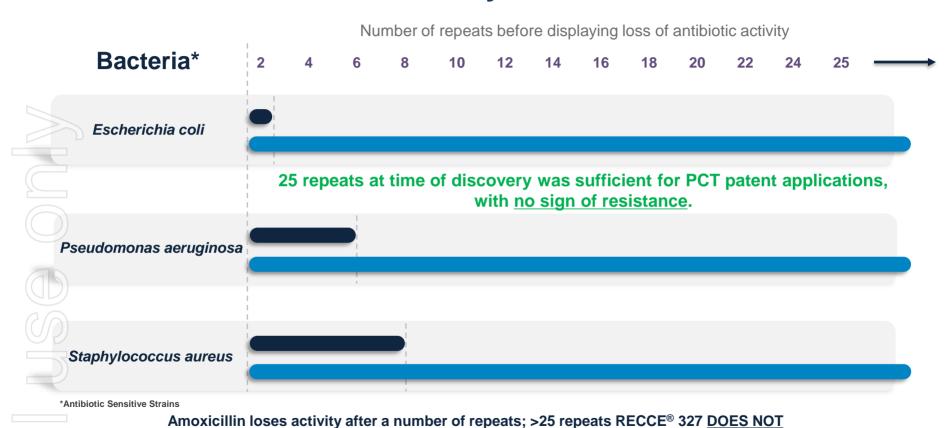






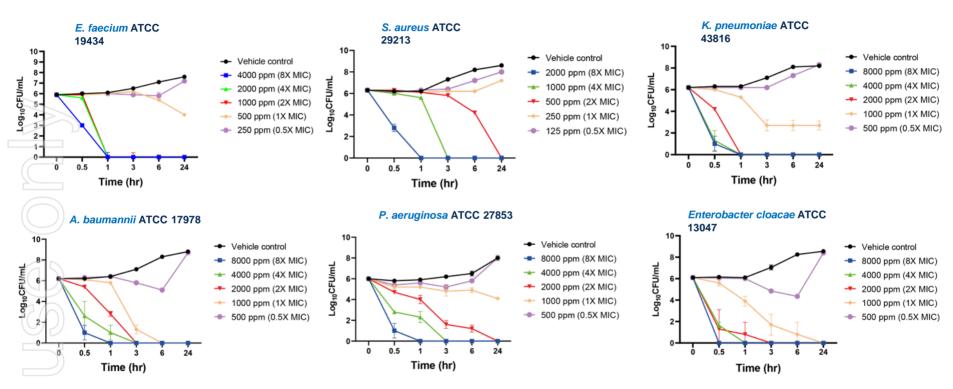
RECCE® 327 Maintains Activity

Amoxicillin



RECCE® 327

Bactericidal Effect of RECCE® 327 on ESKAPE Pathogens

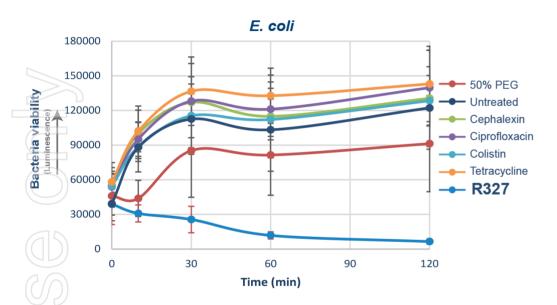


- Average time-kill curves of R327 at various concentrations against strains of ESKAPE pathogens (tested in duplicate)
- Time-kill study was performed to determine the bacterial killing effect of R327 at a total of five concentrations, ranging from 0.5X to 8X, MIC and to measure killing kinetics of treatment 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® 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;



All AF's mild or moderate

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

Concentrations of RECCE® 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

- 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).







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







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
Patient 1	Daily	32/M	Left forefoot lateral aspect	Methicillin-Resistant S. aureus	Escalated therapy*
Patient 2	Second Daily	55/M	Right hallux plantar aspect	S. aureus, mixed skin flora and coliforms	Infection resolved/cured
Patient 3	Second Daily	51/M	Left forefoot plantar aspect	S. aureus, 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





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.



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



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



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



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Pre-Treatment



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





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.

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



Pre-Treatment



Day 0 – Pre-treatment
Significant bacterial infection – septic ankle arthritis, periprosthetic 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.

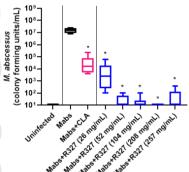
RECCE® 327 Activity Against Multiple Bacterial Infections

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

Intracellular *M. abscessus* (3 dpi)

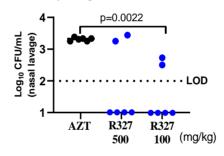


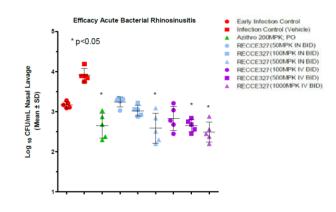
Human stem cell-derived macrophages (SCDM) infected with *M. abscessus* (Mabs) were treated with R327 or clarithromycin (CLA):

- 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.

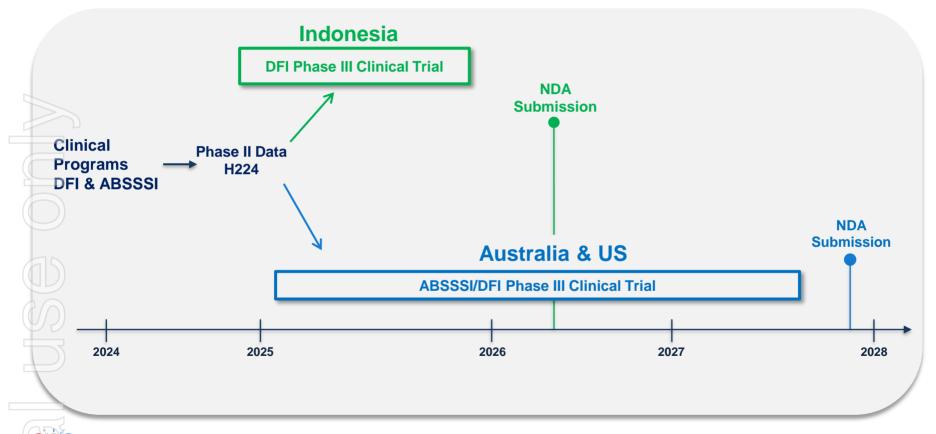
Family 2 relates to the Method of Manufacture, Administration and Application to Treat a Broad Range of Common Human Infections.

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.





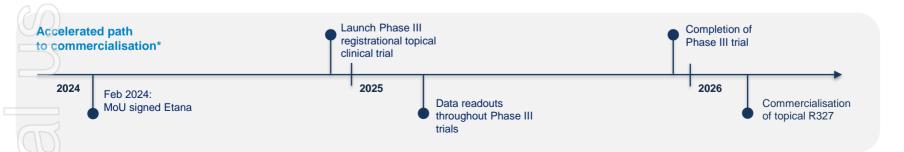
Strategic Opportunity in South-East Asia to Accelerate Clinical Program

- 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)



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) Finding

- 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

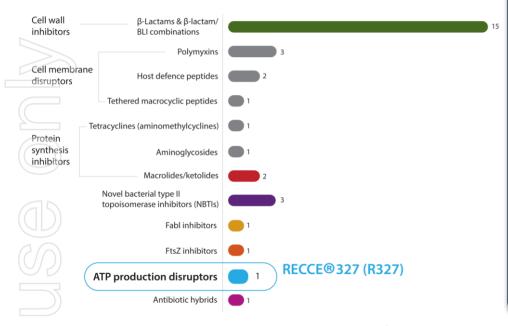
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RECCE® 327 – Global Recognition

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.





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



Thank you





