



Commercialising a New Class of Synthetic Anti-Infectives

RECCE PHARMACEUTICALS LIMITED | (ASX:RCE)(FSE:R9Q)

CORPORATE PRESENTATION | MARCH 2025

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Company Overview



Leading, Australian Anti-Infective Company

Near-term commercialisation pathway expected to launch in 2026



Products address the global healthcare crisis of antibiotic resistance



Phase III in Indonesia of lead asset RECCE® 327 Gel **for the treatment of Diabetic Foot Infections - Launch in 2026 and opens gateway to ASEAN and other markets**



Multiple clinical indications and formulations in Phase I and II **addressing unmet medical needs**



US FDA Qualified Infectious Disease Product designation provides 10 years of market exclusivity plus fast-track approval*



World Health Organization added RECCE® compounds to its list of antibacterial products in clinical development for priority pathogens



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

Synthetic Anti-Infectives

The need for a new class of antibiotics

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



Unprecedented, broad-spectrum activity against Gram +ve and Gram -ve bacteria 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 over \$US9.1 billion



US\$5.2B

Est. global DFI
treatment
market¹

- The DFI treatment market is estimated to be worth ~US\$5.2 billion¹
- Initially targeting Indonesian market valued at ~US\$189 million where DFI impacts 11% of the population²
- 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**³



US\$3.9B

Est. global
sepsis market⁴

- The global sepsis therapeutics market size is anticipated to reach US\$5.64 billion by 2030, growing at a CAGR of 6.18% from 2025 to 2030⁴
- Recce is initially targeting US and Australian markets worth **in excess of US\$1.5 billion**⁴

~US\$135.4B

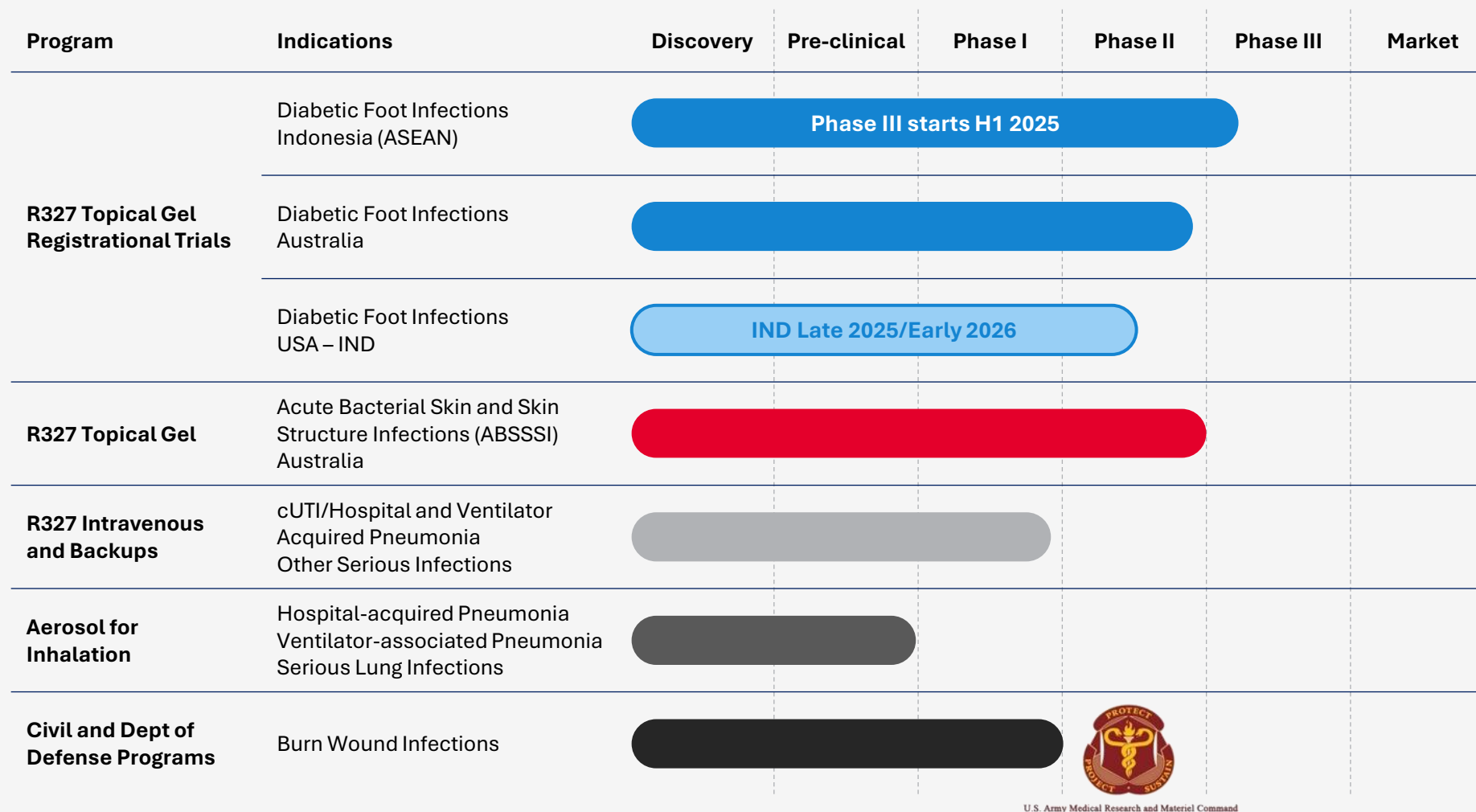
Estimated value of the significant **additional market opportunities** in the broader anti-infectives market

Recce already exploring opportunities in burn wound infections, skin and soft tissue infections post operation⁵

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

Program Pipeline for 2025

Various indications and upcoming inflection points



- Approval received from the Indonesian Drug and Food Regulation Authority, Badan POM, to initiate its Registrational Phase 3 clinical trial in Indonesia
- ABSSSI includes 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

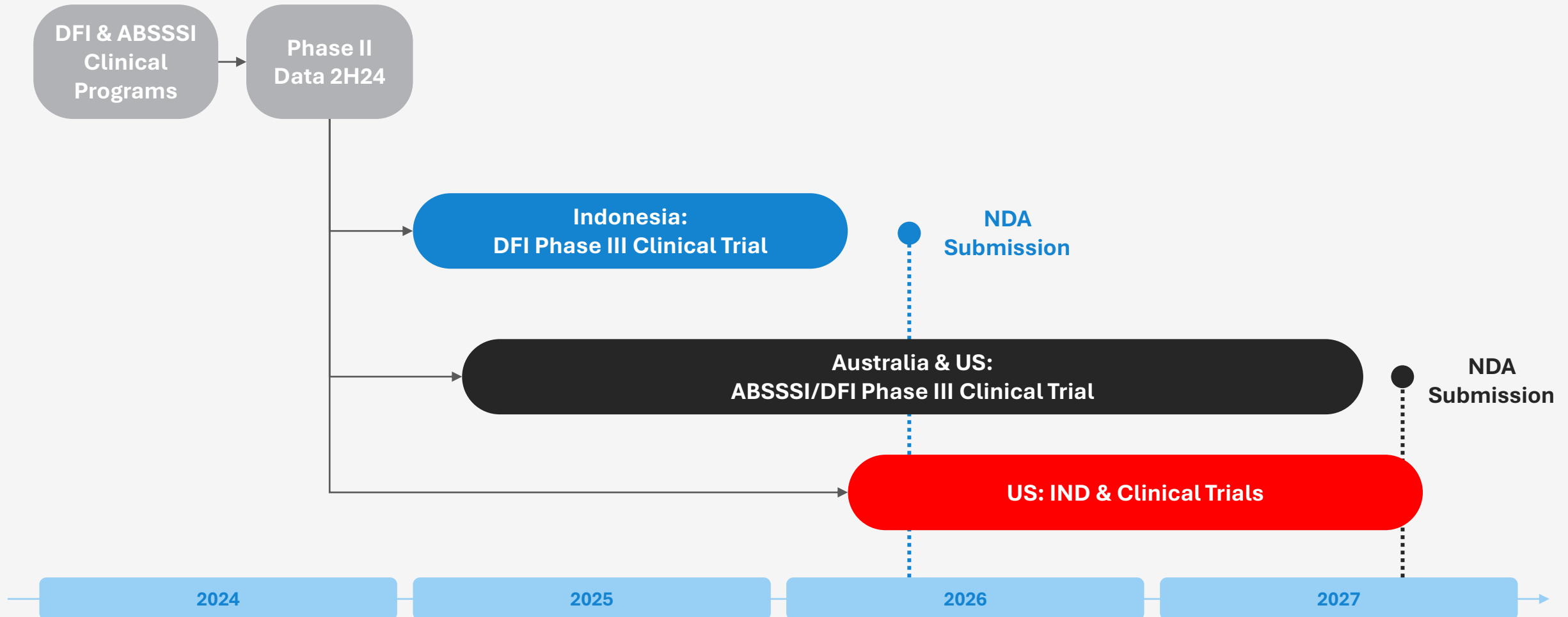
Multiple Clinical Milestones – Achieved and Upcoming

Significant milestones anticipated in 2025

Pre FY2025	Previous 12 Months	2025 and 2026
<ul style="list-style-type: none">✓ Phase I/II Clinical Trial for the Treatment of Burn Wound Infections Phase I complete✓ R327G indicated positive clinical response in the treatment of multiple antibiotic-resistant infections under TGA Special Access Scheme Category A✓ R327 Phase I/II UTI/Urosepsis Rapid Infusion Clinical Trial - safe and well tolerated at faster infusion rates ~30min for 2,500mg and 3,000mg✓ MoU with PT Etana Biotechnologies Indonesia to work collaboratively on R&D, production, distribution and commercialisation of R327	<ul style="list-style-type: none">✓ Phase II Acute Bacterial Skin and Skin Structure Infections (ABSSSI) including Diabetic Foot Infections (DFI) clinical trial complete, meeting all endpoints✓ US Department of Defense grants US\$2.0 million funding to accelerate development of R327 for acute treatment of burn wound infections✓ Regulatory and ethics approval received for Indonesian Registrational Phase III trial in Diabetic Foot Infections	<ul style="list-style-type: none">○ Launch Registrational Phase III trial for DFI in Indonesia○ Launch Registrational Phase III trial for ABSSSI in Australia○ Commencement of US Department of Defence Burn Wound Program○ File Investigational New Drug Application for R327 in the USA○ Launch Phase II UTI/Urosepsis Clinical Trial (with data readouts throughout)

Commercialisation Pathway in DFI and ABSSSI:

Positive Phase II and SAS data → Start Phase III in DFI



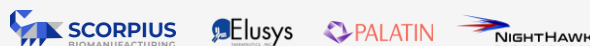
Experienced Board of Directors



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 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.



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). Advanced several blockbuster antibiotics through regulatory review and commercialisation at Fortune 500 companies including Roche. Responsible for the approval of approximately 20 New Drug Applications; an amalgamation of prescription and OTC products.



Alistair McKeough – Non-Executive Director

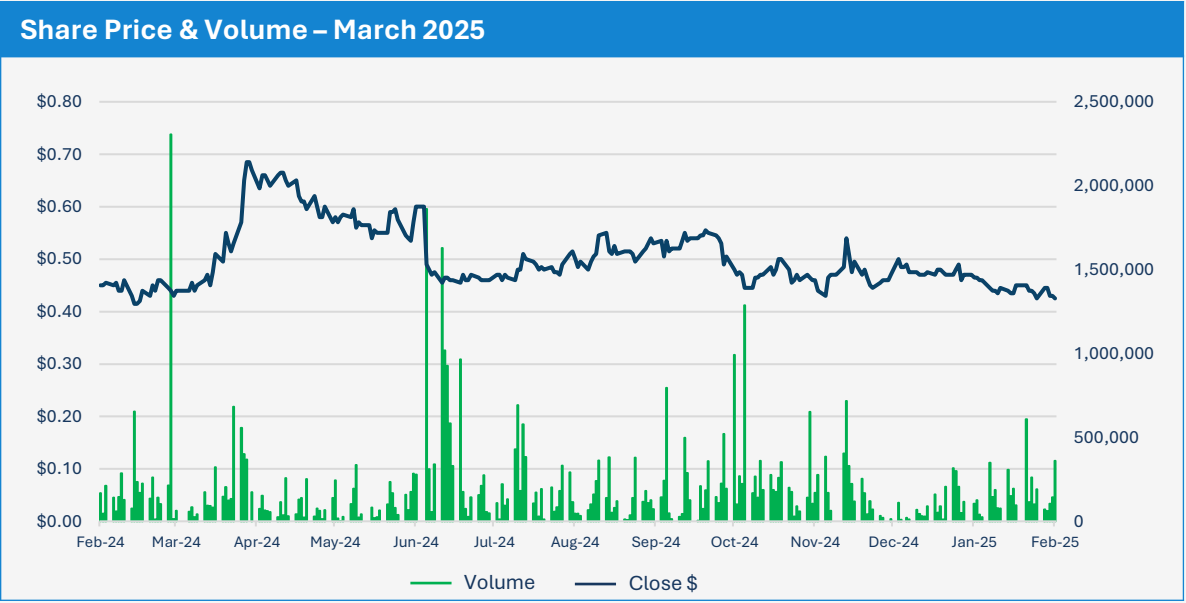
Alistair is a qualified lawyer and specialises in complex commercial matters that require careful and strategic planning. Mr McKeough has extensive experience advising ASX-listed companies and their directors.

Company Overview: Recce Pharmaceuticals Ltd

A clinical-stage Australian biotech company with a new class of synthetic anti-infectives



Capital Structure – March 2025	
ASX & FSE Code	RCE, R9Q
Share Price	AUD \$0.43
3-Month Average Daily Volume	115.49k
Shares on Issue	231.87 million
Unlisted Options (Avg \$1.54)	13.9 million
Market Capitalisation	AUD \$98.5 million
Cash at Bank*	AUD \$1.94 million
Top 20 Shareholders	50%
Debt	Nil



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



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



I.V. and topical treatments advancing for UTI/Urosepsis and Acute Bacterial Skin and Skin Structure Infections (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 ABSSSI, including Diabetic Foot Infections**

*Cash balance does not reflect Q3, 2024 announced U.S. Department of Defence Army burn wound grant of US\$2.0 million (~A\$3 million) or anticipated additional R&D advance funds.

**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

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R327 Solution

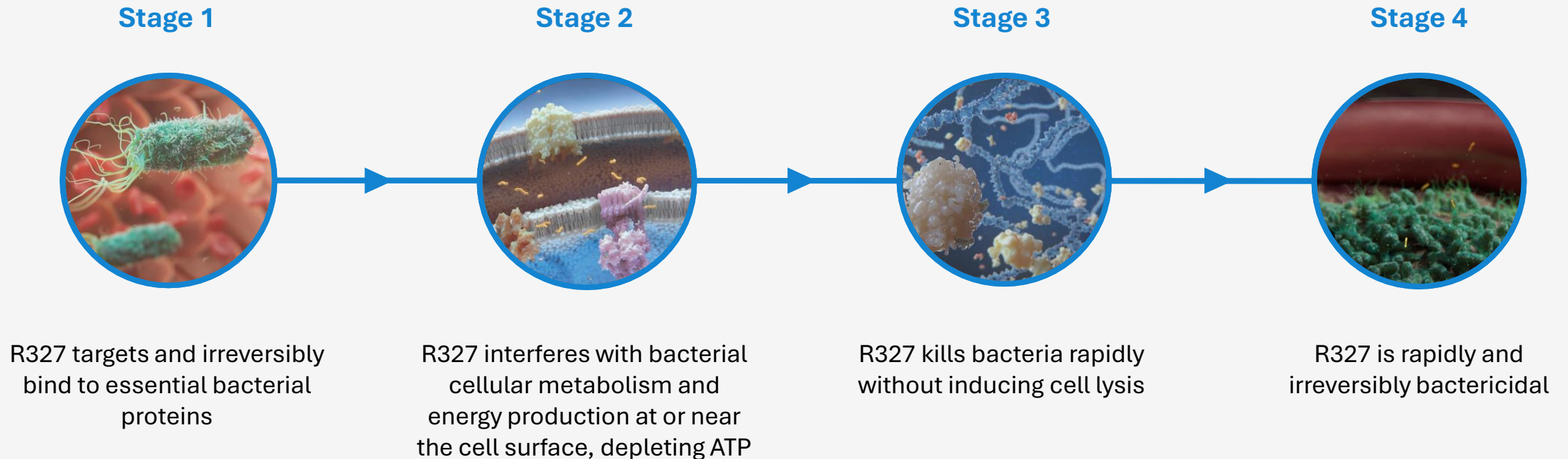


RECCE[®] 327

Independent Study Undertaken on RECCE® 327 MoA¹

Linnaeus Biosciences MoA studies of R327

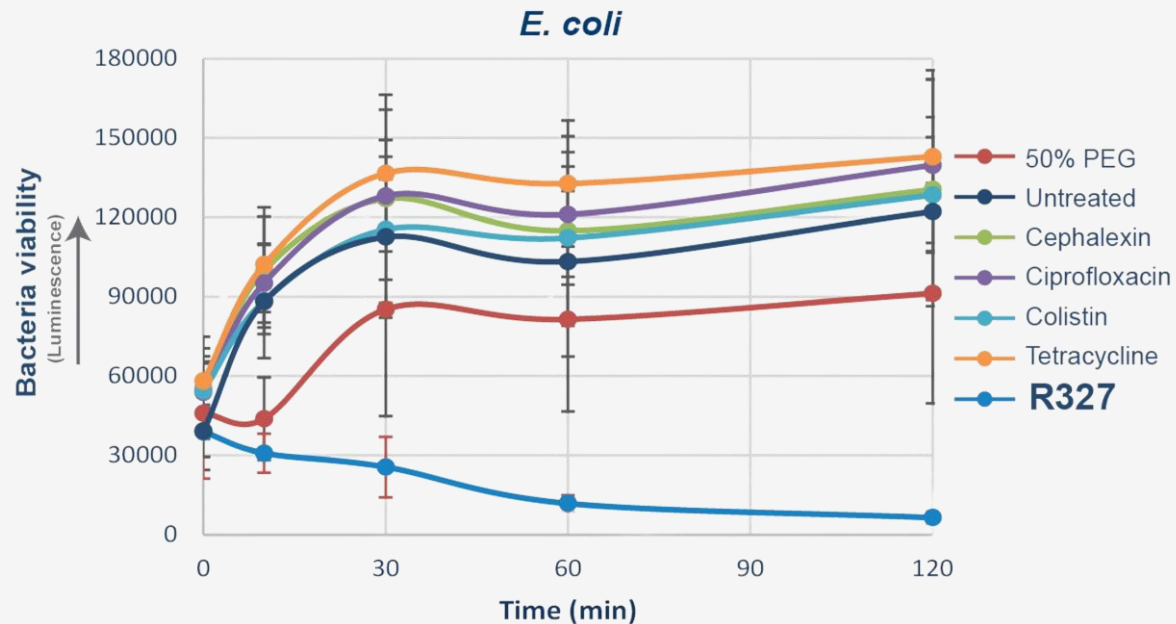
Recce products work via a NOVEL MECHANISM which targets rapid access to and shut down of bacterial energy production (ATP), **which results in bacterial death of both active and resting bacteria**



R327 Faster Acting Than Existing Antibiotics

No prolonged exposure needed

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)



R327 shuts down ATP production, the driver of bacterial energy irreversibly in minutes

Because of its unique MoA, R327 kills pathogenic bacteria at a faster rate than any known antibiotic and it is the only clinical candidate currently being developed to target ATP disruption

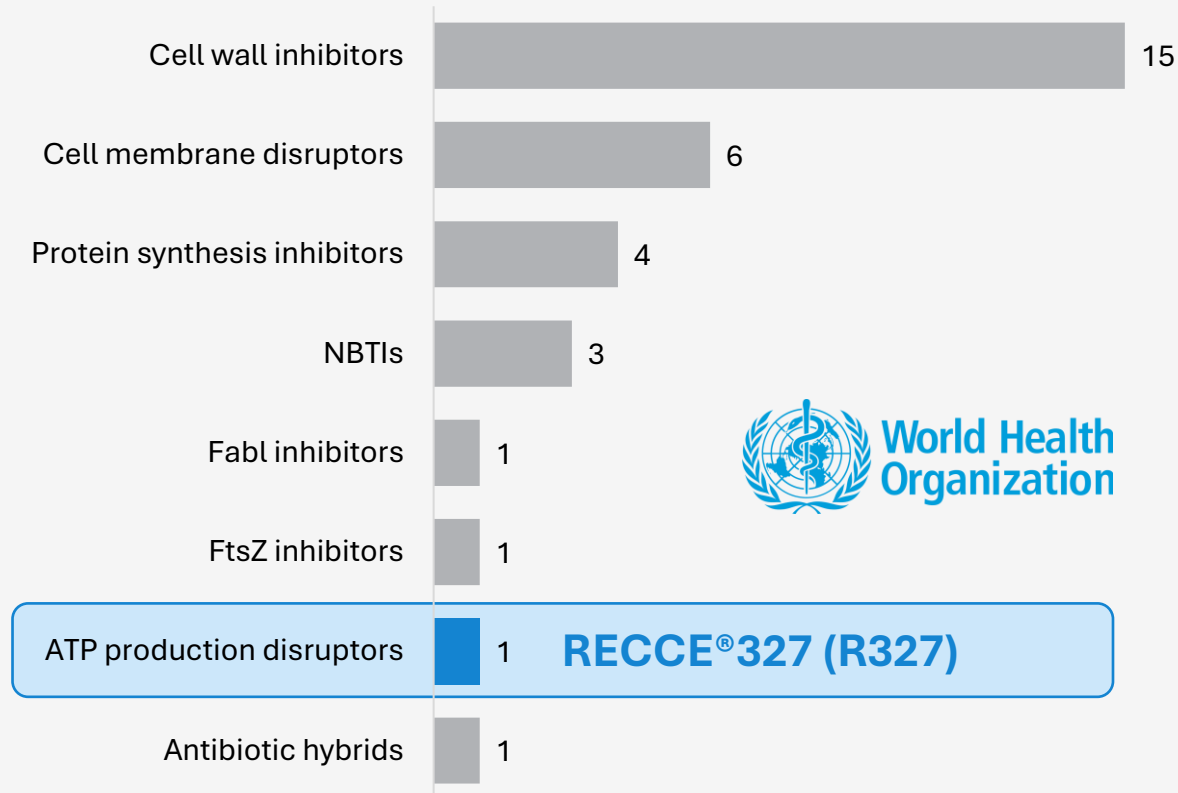
“ R327 kills bacteria in conditions where other antibiotics are ineffective ”

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

RECCE® 327 – Global Recognition

R327 added to WHO's list of antibacterial products in clinical development

Number of compounds by 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

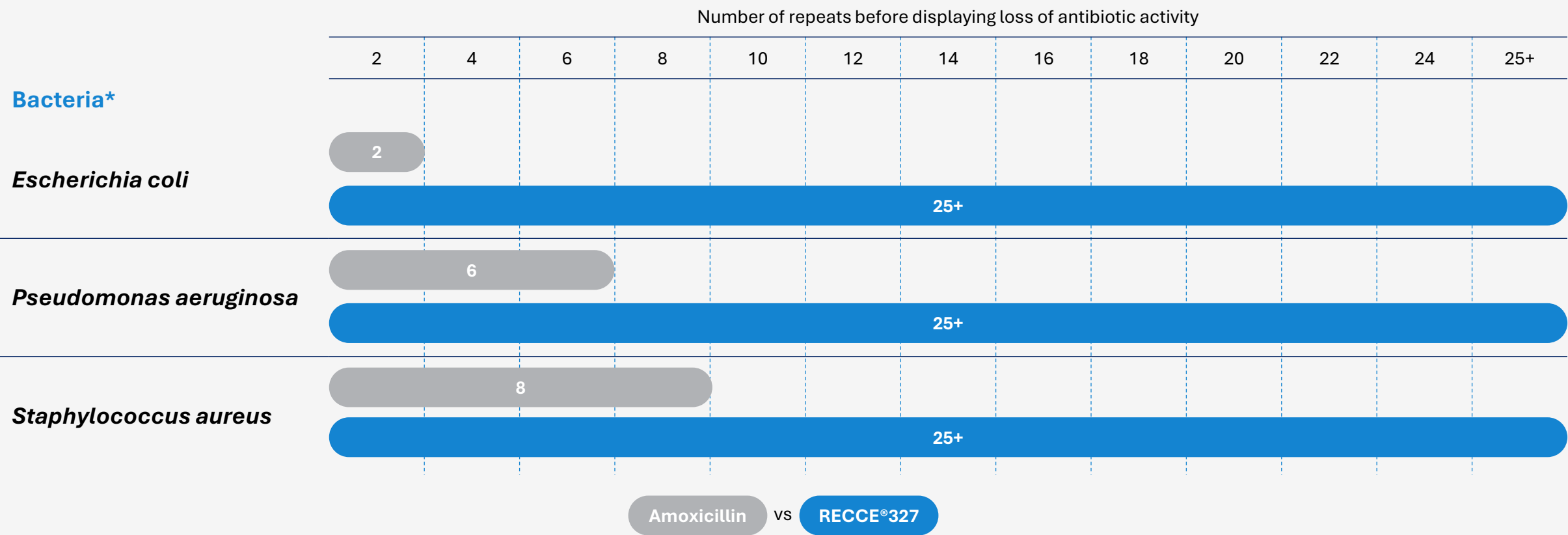
The WHO report covers traditional and non-traditional antibacterial agents in development worldwide and evaluates to what extent the present pipeline addresses infections caused by priority pathogens

RECCE® 327 – NO RESISTANCE on Serial Passaging



Amoxicillin loses activity after a maximum of 8 repeats; [RECCE® 327 remains active for more than 25 repeats](#)

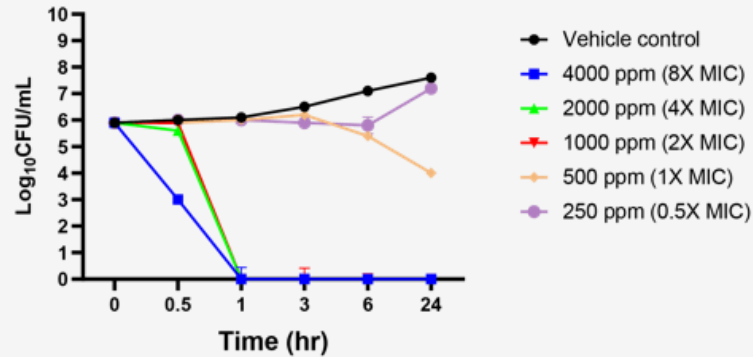
25 repeats at time of discovery was sufficient for PCT patent applications, with [no sign of resistance](#)



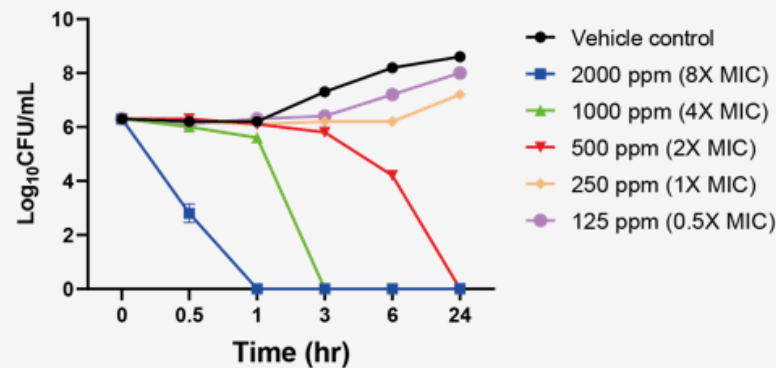
*Antibiotic Sensitive Strains

Broad-Spectrum of Coverage of RECCE® 327 *in vitro* against ESKAPE Pathogens-Bactericidal Effect

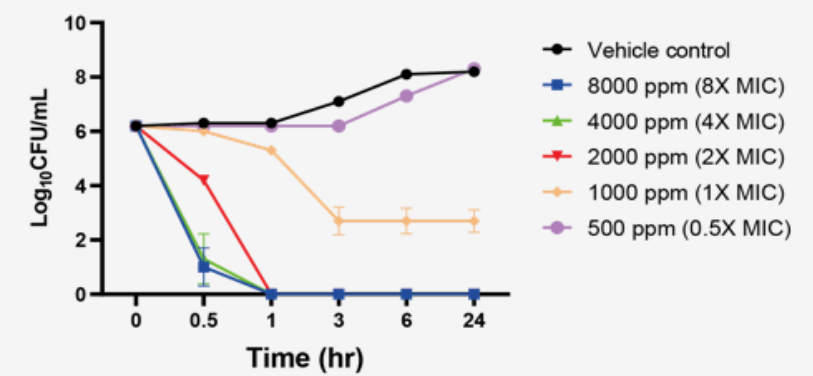
E. faecium ATCC 19434



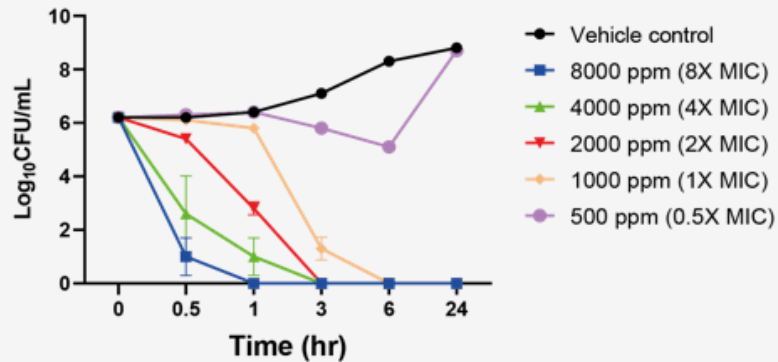
S. aureus ATCC 29213



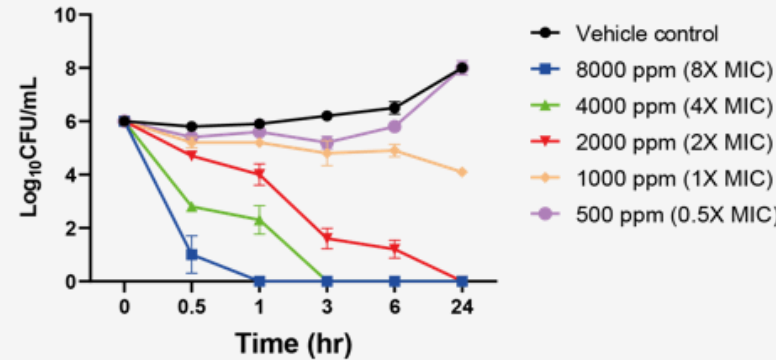
K. pneumoniae ATCC 43816



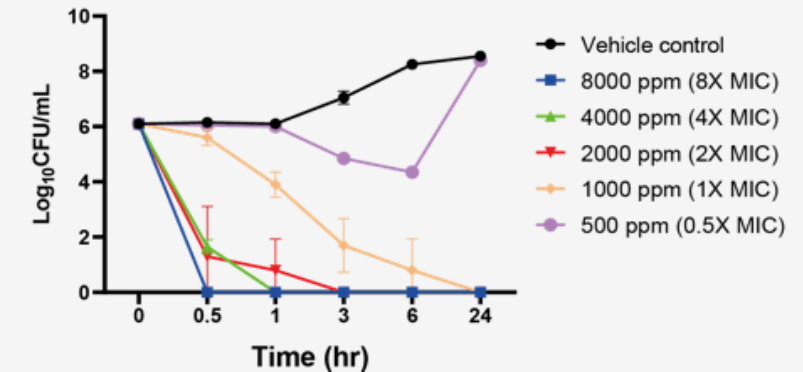
A. baumannii ATCC 17978



P. aeruginosa ATCC 27853



Enterobacter cloacae ATCC 13047



- 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 five concentrations, ranging from 0.5X to 8X, MIC and to measure killing kinetics of treatment with R327 against each strain.

R327 Active Against all Tested Clinical Drug-Resistant Species

Test Bacteria	Antibiotic	# of strains resistant to comparator abx		# of strains resistant to R327
	Comparator abx	Total # of strains	(+/-)	
<i>Klebsiella pneumoniae</i> ¹	levofloxacin	66	52	0
<i>Klebsiella pneumoniae</i> ²	imipenem	35	13	0
<i>Acinetobacter baumannii</i> ³	levofloxacin	67	48	0
<i>Acinetobacter baumannii</i> ⁴	imipenem	17	12	0
<i>Pseudomonas aeruginosa</i>	levofloxacin	85	67	0
<i>Pseudomonas aeruginosa</i>	imipenem	14	10	0

1. Includes resistance genes e.g. KPC (12 strains including 5 strains KPC-2), NDM-1 (11 strains), OXA-48 (3 strains tested), CTX-M (45 strains)

2. includes resistance genes e.g. NDM-1 (4 strains tested); OXA (21 strains tested); CTX-M (24 strains tested); KPC (2 strains tested)

3. includes resistance genes e.g. OXA-23 (25 strains); VIM (1 strain); PER-7 (4 amino acid substitutions compared to PER-1)

4. includes resistance genes e.g. OXA-23## (26 strains), OXA24 (10 strains); TEM-1, armA

**These resistance genes
are from Ukraine
military patients**

R327: Clinical Programs

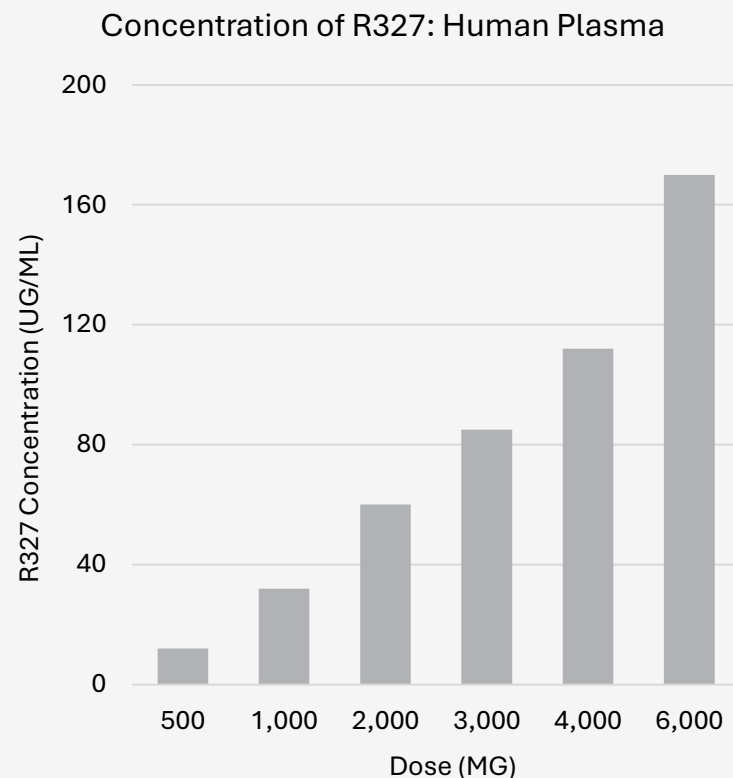
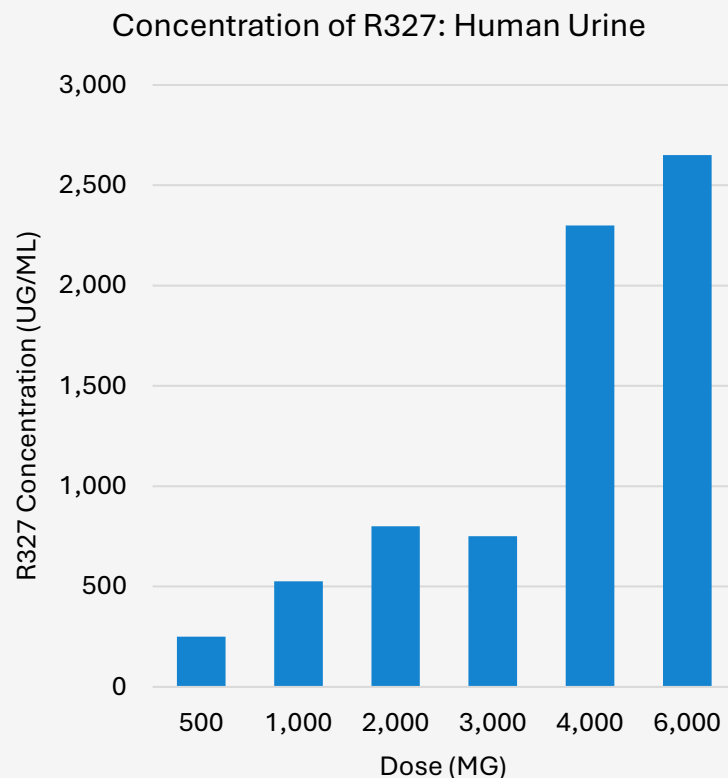
RECCE® 327 Phase I: Safety & PK Intravenous Study

Double-blind, placebo-controlled, single ascending-dose, in 80 healthy participants

- **Safe and well tolerated** at doses up to 4,000mg given as a 1-hour intravenous infusion
- **No Serious Adverse Events:** All AE's mild or moderate (some irritation, discomfort at infusion site mostly at 6,000mg, also in placebo)
- **No changes to outside normal limits** 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 – potential complicated cUTI as an indication



RECCE® 327 Excreted Safely in High Concentration in Urine



- **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

Concentration of R327 in Urine Compared to Plasma (from over 60 healthy subjects)

Dose (MG)	500	1,000	2,000	3,000	4,000	6,000
Ratio Urine/Plasma	16x	17x	14x	9x	21x	16x

Phase I/II UTI/Urosepsis Rapid Infusion Clinical Trial

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

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

Clinical Trial Complete

Assessment	Assessing R327 at faster administration rates (<1 hour) Ability of Collected Urine to kill <i>E. coli</i> Bacteria (<i>ex vivo</i>)
Endpoint	No serious adverse events reported and no clinically significant changes in any laboratories, reinforcing safety profile of R327 Provided proof of ability in urine collected from volunteers dosed with R327 to kill <i>E. coli</i> (<i>ex vivo</i>)
Subjects	Male and female subjects dosed
Initial indication	Results from trial paves the way for R327 as a potential first-line treatment for patients suffering from UTI/Urosepsis
US FDA status	Qualified Infectious Disease Product designation - awarded by the US FDA in 2017 for R327 bacteraemia (broad-spectrum bacterial sepsis).

15 minutes

20 minutes

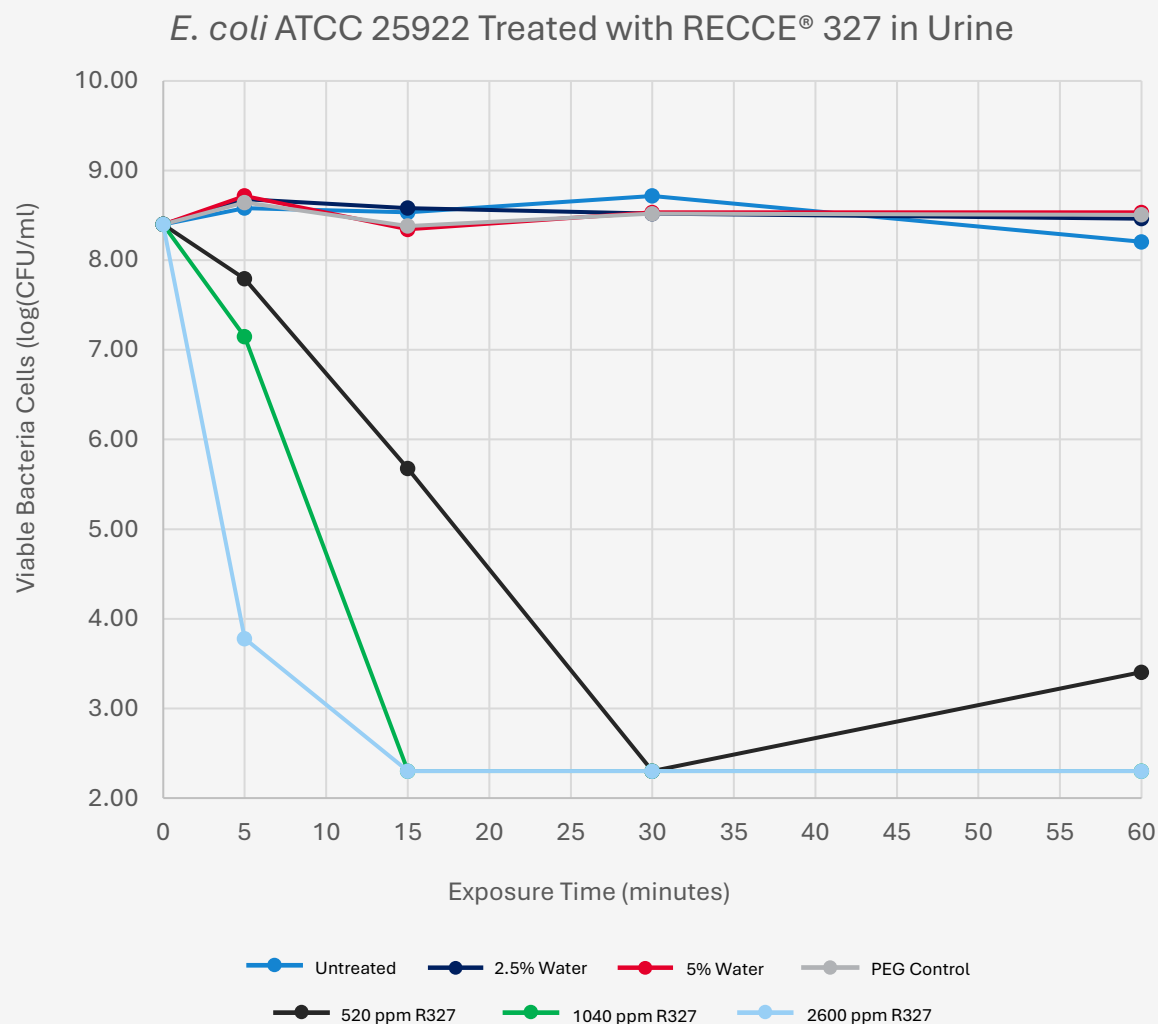
30 minutes

45 minutes

1 hour



RECCE® 327 Kills Quickly in the 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/>

R327: Topical Spray and Gel

Patient Case Study – TGA Special Access Scheme

Day 0:
Pre-treatment



Day 0:
First Recce gel applied



Day 1:
Post treatment



Day 30:
Post treatment



Patient unresponsive to 4x daily Cephalexin for 10 days:
Infection spreading and hospital ready

After only one dosing of R327, the infection had clinically responded in 24 hours – 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

Infection with Biofilm



Pre-treatment (Day 0) X-rays showed **infection deep within the underlying bone**, tissue and around the nail, with signs of initial biofilm formation

After 3 days of R327G treatment, the wound is **drying up with infection clearing** and the toe responding well to treatment

- ✓ Day 7 post R327G treatment showed wound completely dried up, no signs of biofilm surrounding toenail and swelling significantly reduced
- ✓ Surgical intervention, which was the next step for this patient, was averted

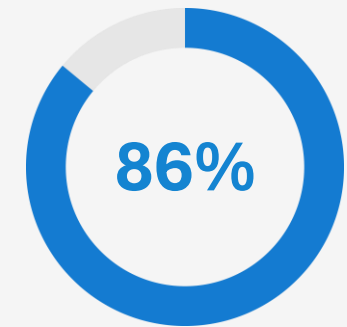
Phase II DFI / ABSSSI Clinical Trial – Achieved all Endpoints

Confirms approach for Phase III trials and commercialisation progress in Australia

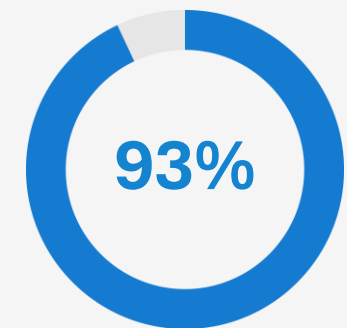
- This Phase II study **achieved all primary and secondary endpoints** as an open-label clinical trial evaluating the safety and tolerability, efficacy, and plasma pharmacokinetics of R327G when applied directly to the infected area
- The study enrolled 30 patients, with 29 included in the final data analysis. One patient was withdrawn due to pre-existing pain at the wound site that was deemed unrelated to R327G
- After 7 days of treatment, **86% of patients** (25 out of 29) treated with R327G had a successful clinical response
- At 14 days of treatment, **93% of patients** (27 out of 29) achieved a primary efficacy endpoint
- **R327G demonstrated to be safe and well tolerated, achieving all endpoints - no Serious Adverse Events reported**

Successful clinical response

After 7 days of treatment



After 14 days of treatment



Study Outcome – Top Line Data*	To evaluate the efficacy of RECCE® 327 topical gel on ABSSSI
Assessment method	Lipsky Scale/Bates Jensen Wound Assessment Tool
Endpoint met	Yes

*<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=387997&isReview=true>

RECCE® 327 Topical Gel: Phase III Registration Trial in DFI

R327G Multicenter study in Indonesia



- Double blind, Placebo-controlled, Parallel group Study in Patients with DFI
- Drug to be administered once daily at the clinic for up to 14 days
- N=300 patients (200 active, 100 placebo)
- Planned enrolment to be conducted at up to 10 centers across Indonesia
- **Primary endpoint is “clinical response” – per standard used by US FDA and other regulatory authorities for this indication and consistent with Phase II study**
- ***Interim analysis at 106 patients completed (est. 1QCY26) with success the catalyst for accelerated review and approval***



Commercialisation Opportunity



Recce Global Growth Strategy



**Expansion into
ASEAN**



**Expansion
across
Australia/NZ**



**Expansion to
USA/DoD**

**Global
Approvals**

Gel

IV

Aerosol

**New Products
and New
Indications**

DFI Gel
ABSSSI Gel
Burn Gel

IV cUTI
IV Sepsis
IV HAP & VAP
IV Single Dose UTI

Aerosol HAP / VAP
Aerosol non-TB
Mycobacteria
Intranasal Sinusitis

Strategic Partnership in SE Asia to Accelerate Clinical Program

Phase III Registrational Clinical Trial in Indonesia Topical Gel

- **Approval received from the Indonesian Drug and Food Regulatory Authority, Badan POM,** to initiate registrational Phase III clinical trial
- **Human Research Ethics Committee approval received** – registrational Phase III clinical trial to commence this quarter

Opportunity Presents a Clear Path to Commercialisation

- **Awarded expedited regulatory review status in Indonesia to fast-track progression of Phase III trial;** brings forward commercial opportunities in ASEAN region
- **Opportunity to access 10 ASEAN member states** covering a population of 680 million inhabitants
- **Significant bilateral initiative** supported by Australian and Indonesian Governments
- **Memorandum of Understanding (MoU)** with leading biomedical company PT Etana Biotechnologies (Etana) to **facilitate late-stage clinical trials** in Indonesia, supporting the Indonesian Government's access to novel infectious disease medicines
- **Expected launch in 2026**



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

Manufacturing & Scalability for Commercialisation

- Key raw ingredient made in the USA
- Clinical Phase I-II and preclinical product produced at RECCE Macquarie Park facility in Australia
- GMP Manufacturing facility in Australia for Phase III/Scale up
- Exploring US manufacturing opportunities for large scale
- Raw materials **plentiful and cheap** – few \$/Kg
- **No expensive waste** – 99.9% product yield



Robust Worldwide Intellectual Property Portfolio

Patent portfolio of 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	✓	2041
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)

Summary

Significant value creating opportunities



Novel, Synthetic, Broad-Spectrum,
Rapid-Acting, Anti-Infectives:
**demonstrated against >500 clinical
isolates** including all resistant species;
no signs of resistance to R327



**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**



**Development of a first new class of
antibiotic in over 40 years**, recognised
by the World Health organisation, with
accelerated de-risking via registrational
Phase III trials in Indonesia and Australia



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



Thank You

James Graham

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