# RCE Corporate Presentation

ASX:RCE | FSE:R9Q

Annual General Meeting 2025

November 2025

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# Recce Pharmaceuticals – Company Overview



*An Australian clinical-stage biotech with a United States presence, developing a New Class of Synthetic Anti-infectives with a unique mechanism of action for a broad spectrum of infections including serious/life-threatening indications.*

Publicly-traded on the **Australian and Frankfurt exchanges – (ASX: RCE, FSE: R9Q).**

**Therapeutics to address the global healthcare crisis** of antibiotic resistance: works faster than traditional antibiotics and against multidrug-resistant bacteria.

**Phase 3 Clinical trial (Indonesia) – patient dosing commenced.**

Multiple successful Phase I and Phase II clinical trials across Australia.

US Defense Burn Research Program grant; US Army Medical Research Institute of Infectious Diseases – **in progress.**

**>40 granted patents** across major pharmaceutical markets out to 2041.

**Our goal is for our product to be made available in Indonesia in 2026.**

**RECCE® 327 granted Qualified Infectious Disease Product (QIDP) Designation by U.S. Food and Drug Administration giving 10 years market exclusivity plus fast-track approval.**

**RECCE®327 added to World Health Organization's List of Antibacterial Products in Clinical Development.**

# Board and Management Structure



## Dr John Prendergast – Chairman

*BSc (Hons), MSc (UNSW), PhD (UNSW), CSS (HU)*

US-based biotechnology executive and investor with extensive experience in the commercialisation, financing, and sale of pharmaceutical assets. He has overseen three New Drug Approvals and led multiple licensing and M&A transactions, including the successful sale of Vyleesi® to Cosette Pharmaceuticals for USD $159 million in contingent, sales-based milestones. Over his career, he has been instrumental in capital raises exceeding USD $1 billion and has directed numerous transactions involving the sale of assets, technologies, and companies across the biotechnology and healthcare sectors.

SCORPIUS BIOMANUFACTURING · Elusys · PALATIN · NIGHTHAWK BIOSCIENCES

## James Graham – Managing Director & Chief Executive Officer

*BCom (Entrepreneurship), GAICD*

Mr Graham is the Chief Executive Officer of Recce Pharmaceuticals. He brings extensive experience in marketing, business development, and the commercialisation of early-stage technologies with global potential. With a proven track record of growing globally focused companies, Mr Graham has applied his expertise to Recce, including serving on its Board of Directors. He has participated in nearly every capital raise to date, demonstrating a strong commitment to expanding Recce's commercial opportunities and clinical programs.

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

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

US-based pharmaceutical executive with more than 30 years of experience in drug development and commercial leadership. Former President and Managing Director of Janssen Research Foundation (Johnson & Johnson), he directed the approval and launch of around 20 New Drug Applications, including Levaquin®, Regranex®, Aleve®, Procrit®, Sporanox®, Reminyl® and Risperdal®. He has held senior roles at Roche, CIBA-GEIGY, Syntex and Purdue Pharma, and served as CEO of Panacos, Metaphore and EpiCept Pharmaceuticals, overseeing multiple corporate transactions and the successful sale of Vyleesi® to Cosette Pharmaceuticals for USD $159 million in contingent, sales-based milestones.

janssen · PALATIN · Roche · Johnson & Johnson

## 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.

Pfizer

## Alistair McKeough – Non-Executive Director

Mr McKeough is an experienced executive and solicitor. Before being appointed as a non-executive director in 2022, Alistair served as Recce's company secretary and he has been involved with the company since 2017. Alistair has extensive experience in a variety of private and listed corporations across many sectors, including professional services, technology, financial services, charities, health, biotech, childcare and education. Recent roles include Managing Director of a legal practice specialising in equity capital markets and advice to listed companies and as part of the senior leadership team at share registry, Automic Group.

# Leading, Australian Anti-Infective Company

*Near-term commercialisation pathway expected to launch in 2026*



**Products address the global healthcare crisis** of antibiotic resistance

**Phase 3 in Indonesia of** lead asset RECCE® 327 Gel **for the treatment of Diabetic Foot Infections – Expected 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*

# Company Overview

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



| Capital Structure – October 2025 | |
|---|---|
| ASX & FSE Code | RCE, R9Q |
| **Share Price** | **AUD $0.405** |
| 3-Month Daily Average Daily Volume | 114.94k |
| **Shares on Issue** | **289.18 million** |
| Unlisted Options (Avg $1.087) | 24.17 million |
| **Market Capitalisation** | **AUD $121.46 million** |
| Top 20 Shareholders | 53.64% |

*Non-Dilutive Financing via debt facility of up to **~A$30 million** with Avenue Capital Group.

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 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**

*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

# Executive Overview

***Currently only 6 companies on the ASX are conducting Phase III therapeutic trials***



| | |
|---|---|
| Telix Pharmaceuticals **(ASX: TLX)** | 5.44B |
| Mesoblast **(ASX: MSB)** | 3.22B |
| Neuren Pharmaceuticals **(ASX: NEU)** | 2.75B |
| Opthea **(ASX: OPT)** ** | 821M |
| Dimerix **(ASX: DXB)** | 306M |
| Paradigm Biopharmaceuticals **(ASX: PAR)** | 180M |
| Recce Pharmaceuticals **(ASX: RCE)** | 123M |
| Avita Medical **(ASX: AVH)** ** | 98M |
| Amplia Therapeutics **(ASX: ATX)** ** | 72M |

**Significant potential for value creation in next 12-18mos**

** Not started or failed

** A medical device

# 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

# Since Last AGM – Clinical Trial Progress



## ALL Objectives Achieved from last AGM

**Phase II ABSSSI Clinical Trial**
*Topical*
**Trial Data Released**

- ✓ Phase II Clinical Trial data successfully demonstrated R327G achieving a 93% primary efficacy endpoint over 14-days, meeting all study endpoints.
- ✓ Phase II Clinical Trial receives approval for additional diabetic patients to be treated with R327G.

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

- ✓ **Patient dosing is now underway** with five (5) clinical study sites activated across Indonesia. **Trial designed to enrol up to 310 patients,** assessing clinical response according to the Lipsky Scale.

## New Objectives for 2025/2026

**Phase III DFI Clinical Trial**
*Topical Gel*
**Phase III Indonesia Interim data readout Q1 2026 potential market approval mid 2026**

**Phase III ABSSSI Clinical Trial**
*Topical Gel*
**Launch Registrational Phase III trial for ABSSSI in Australia**

**Dept. of Defense Burn Wound Programs**
*Topical Gel*
**Advance across three US Defense Programs**

# 2025/2026 Corporate Goals

## Delivery of Phase 3 Clinical Data

**Expected Interim data readout Q1 2026; potential market approval mid 2026**

## Global Expansion into High-Growth Healthcare Markets

**Regulatory approvals in ASEAN, Middle East (MENA region)**

## Military Partnerships and Grant Funding

**Funding, R&D partnerships, licensing, grant submissions**

## Commercial Partnerships

**Advancing clinical evaluation, registration, and potential commercialisation of Recce's proprietary anti-infective portfolio**

# Strategic Opportunity in South-East Asia

***Awarded expedited regulatory review status in Indonesia to fast-track progression of Phase 3 trial***

**Phase 3 Registrational Clinical Trial in Indonesia Topical Gel**

- **Patient dosing is now underway** with five (5) clinical study sites activated across Indonesia. **Trial designed to enrol up to 310 patients,** assessing clinical response according to the Lipsky Scale.
- **Opportunity to access 10 ASEAN member states** – 680 million inhabitant, including 280 million in Indonesia.
- **Memorandum of Understanding (MoU)** with leading Indonesian biomedical company PT Etana Biotechnologies.

**Opportunity Presents an Innovative Path to Global Access**

- **Significant bilateral initiative** supported by Australian and Indonesian Governments.
- **Expected launch in 2026 in ASEAN region.**
- **Multiple therapeutics** for **unmet medical needs** expected to follow such as: tuberculosis, post-op infections, burn wounds etc.

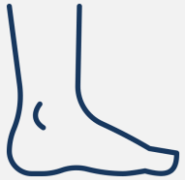
*Recce & Badan POM Team's - Recce CEO James Graham (centre left) and Head of Drug and Food Authority Badan POM, Professor Taruna Ikrar (centre)*

# Registrational Phase III Clinical Trial - Indonesia

***Title: Phase III, Double-blind, Placebo-Controlled Study of R327 Topical Gel for the Treatment of Diabetic Foot Ulcer Infections***



## Population



**Up to 310 participants,** participants will be enrolled who present with a mild diabetic foot ulcer infection.

**Interim data analysis to be conducted after 155 participants.**

## Intervention


Participants to receive either **R327 topical gel** or **placebo topical gel**.

## Locations

**Multi-centre, 5 activated sites across Indonesia.**

Over 20.9 million adults in Indonesia are living with diabetes – more than 1 in every 10 adults.

## Endpoints

**Primary Endpoint:** Assess the **clinical response** of the DFI according to the Lipsky Scale.

**Secondary Endpoints:** DFI total **wound score and safety** of R327G.

***Expected Interim data readout Q1 2026; potential market approval mid 2026***

# Diabetic Foot Infections - Large Addressable Market




- Significant near-term opportunity for Recce with registrational Phase 3 trials anticipated to be completed in FY26 paving the way for future revenues
- **Opportunity to access 10 ASEAN member states** covering a population of 670 million inhabitants
- Initially targeting Indonesian market valued at ~US$189 million where DFI impacts **11% of the population[2]**


- Indonesian approvals provide access to the broader Asia Pacific market worth **~US$1.0 billion per year[3]**
- In Indonesia, DFIs are severe resulting in amputation in **46.9% of hospitalised patients[4].**
- In-hospital treatment costs averaging **USD ~$4,100 per patient** and significantly higher costs for amputees, highlighting the substantial clinical and economic burden of DFI on the national health system[5]

**~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 operation[4]



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) Grand View Research, Anti-Infective Agents Market Size, 2023 5. https://doi.org/10.1016/j.heliyon.2024.e41263

# Military Partnerships and Additional Funding



## US Military Engagement

**U.S. Department of Defense Burn Wound Program**

- U.S. Department of Defense Grants Recce Pharmaceuticals **US$2 million** to accelerate development of R327G for acute treatment of burn wound infections

**Defense Threat Reduction Agency (DTRA) Backed Cooperative Research & Development Agreement with United States Army Medical Research Institute of Infectious Diseases (USAMRIID)**

- Testing R327 against highly hazardous pathogens of biodefense concern in USAMRIID under high biocontainment conditions.

## Non-dilutive Funding

**Non-Dilutive Financing via Debt Facility with Avenue Capital Group**

- Debt facility of up to ~A$30m (US$20m) established with Avenue Capital Group
- Funding to support two Registrational Phase 3 clinical trials in Indonesia and Australia, including manufacturing, regulatory submissions, and market launch preparation for R327G.

**Canadian Scientific Research & Experimental Development Rebate**

- US$175,122 (A$271,987) from the Canadian Government received.

# Phase II ABSSSI Clinical Trial

*Achieved all Endpoints*

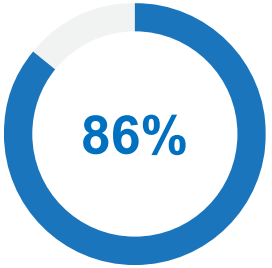
- This Phase II study **achieved all primary and secondary endpoints** as an open-label clinical trial evaluating the safety and tolerability, efficacy, and plasma pharmacokinetics of R327G when applied directly to the infected area
- The study enrolled 30 patients, with 29 included in the final data 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

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

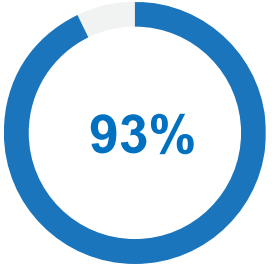
*https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=387997&isReview=true

**Successful clinical response**

*After 7 days of treatment*




*After 14 days of treatment*



# 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 | ✓ | 2041 |
| China | ✓ | 2028 | ✓ | 2037 | ✓ | 2037 | ✓ | 2041 |
| 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 3 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 3 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 3 trials in Indonesia and Australia

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

# Thank you

**James Graham**
Managing Director and Chief Executive Officer
Recce Pharmaceuticals Ltd
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