# **FACT SHEET**

RECCE PHARMACEUTICALS LTD (ASX:RCE, FSE:R9Q)

#### **SEPTEMBER 2025**

# An Emerging Global Leader in a New Generation of Anti-Infectives

Recce Pharmaceuticals Ltd (ASX:RCE, FSE:R9Q) is an Australian clinical stage biotech company engaged in the development and commercialisation of a new class of Synthetic Anti-infectives designed to address the urgent global health problem of antimicrobial resistant (AMR) superbugs.

Recce's lead candidate, RECCE® 327 (R327), is a patented, broad-spectrum synthetic anti-infective being developed in multiple formulations, including intravenous and topical. It is designed to treat serious bacterial infections, including those caused by drug-resistant **Gram-positive** and **Gram-negative** pathogens.

R327 as a Topical Gel (R327G) is currently advancing through late-stage clinical development, with a particular focus on addressing diabetic foot infections (DFIs), a major complication of diabetes and a significant global health burden. Recce is also advancing a broader portfolio of synthetic anti-infectives targeting a range of unmet medical needs across bacterial and viral infections.

The Company's lead clinical program involves a registrational Phase 3 clinical trial of R327G for the treatment of DFIs, conducted in Indonesia. The trial is designed to generate pivotal safety and efficacy data and serves as a potential gateway to broader regulatory and commercial opportunities across the ASEAN market.

The Company also has a Cooperative Research and Development Agreement signed with US Army Medical Research Institute of Infectious Diseases, to test R327 against biothreat pathogens in established *in vitro* models targeting burn wound infections.

Recce's fully owned, automated manufacturing facility in Australia supports ongoing clinical development and scale-up. With a strong global patent portfolio and a targeted focus on unmet medical needs in diabetic wound care, Recce is advancing a next-generation anti-infective platform poised for near-term commercialisation and global expansion.

## **Corporate Summary**

- Proprietary New Class of Anti-Infectives against bacteria and viruses, protected by Composition of Matter Patent.
- World's Most Clinically Advanced New Class of Anti-Infectives focussed upon the urgent global health threat of antibiotic-resistant superbugs.
- Multiple Clinical Trials Complete, others underway Broad spectrum therapeutic potential for major unmet medical needs of Sepsis/Urosepsis, Burn Wound Infections, ABSSSIs, Diabetic Foot Infections and more
- R327 bactericidal activity against all ESKAPEE pathogens.
- R327 cleared for use under Therapeutic Goods Administration (TGA) Special Access Scheme (SAS) - Category A
- Global recognition by the World Health Organization –
  inclusion underscores significance of R327 in combating AMR.
  R327 uniquely classified as an adenosine triphosphate (ATP)
  production disruptor, the only compound under this category
  development for priority pathogens, recognising Recce's
  efforts to combat antimicrobial resistance.
- R327 has been awarded Qualified Infectious Disease Product (QIDP) designation by the U.S. FDA under the GAIN Act, providing Fast Track status and 10 years of market exclusivity post-approval.
- Australian Government awarded AUD \$54,947,284
   (USD \$37,043,433) Advanced Overseas Finding\* across RCE infectious disease portfolio\*



#### **SNAP SHOT**

Ticker	ASX:RCE, FSE:R9Q				
Date listed	January 2016, March 2021				
52 week range	AUD \$0.2750 - A\$0.5700				
Market Cap	AUD \$121.46m (priced at \$0.4200)				
Cash balance*	A\$10.53m				
Shares on issue	289.18m				
3 month avg. vol	131.94K (per trading day)				
Sector	Pharmaceuticals, Biotechnology & Life Sciences				

<sup>\*</sup>Recently successful equity capital raising of **A\$15.8m** and Non-Dilutive Financing via Debt Facility with Avenue Capital Group of **-A\$11.5m** 

#### **BOARD AND MANAGEMENT**

Dr John Prendergast Executive Chairman

James GrahamManaging Director & Chief Executive OfficerMichele DiliziaExecutive Director & Chief Scientific OfficerDr Justin WardExecutive Director & Principal Quality ChemistDr Alan W DuntonChief Medical Advisor & Non-Executive Director

Alistair McKeough Non-Executive Director Arthur Kollaras Head of Manufacturing

 Justin Reynolds
 CFO (Outsourced - Pitcher Partners Sydney)

 Maggie Niewidok
 Company Secretary (Outsourced - Kardos Scanlan)

### **PATENT PORTFOLIO**

Patents covering the manufacturing process run until 2029. Granted provisional patents covering additional modes of delivery and anti-viral uses, run until 2037.

Recce Pharmaceuticals Ltd patent portfolio has continued to strengthen with granted patents in key pharmaceutical markets such as USA, Europe, Japan, China and Australia.

FILED	PATENT FAMILY 1	EXPIRY	PATENT FAMILY 2	EXPIRY	PATENT FAMILY 3	EXPIRY
Australia	~	2028	<b>~</b>	2037	~	2037
USA	~	2029	<b>~</b>	2037	<b>~</b>	2037
Europe	<b>~</b>	2028	<b>~</b>	2037	<b>~</b>	2037
Germany	~	2028	<b>~</b>	2037	<b>~</b>	2037
Spain	~	2028	<b>~</b>	2037	<b>~</b>	2037
France	~	2029	<b>~</b>	2037	<b>~</b>	2037
UK	<b>~</b>	2028	<b>~</b>	2037	<b>~</b>	2037
Italy	~	2028	<b>~</b>	2037	<b>~</b>	2037
Sweden	<b>~</b>	2028	<b>~</b>	2037	<b>~</b>	2037
Japan	<b>~</b>	2028	<b>~</b>	2037	<b>~</b>	2037
China	<b>~</b>	2028	<b>~</b>	2037	<b>~</b>	2037
HK	Pending	2028	Pending	2037	~	2037

Patent Family 1 - Granted

Unique and highly economical manufacturing process

Patent Family 2 - Pending/Granted

Applications (Multi-drug delivery)

Patent Family 3 - Granted

Anti-viral use

Patent Family 4 - Pending/Granted

Process for Preparation of Biologically Active Copolymer

Australia, Israel, Canada - Granted

Other Patent Cooperation Treaty - pending/allowed



#### RECCE® 327 Mechanism of Action



Stage 1
R327 targets and irreversibly bind to essential bacterial proteins



Stage 2
R327 disrupts bacterial metabolism and depletes ATP at the cell surface

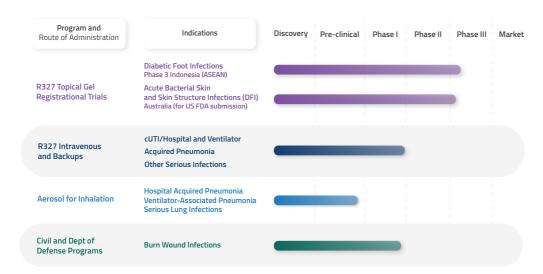


Stage 3
R327 kills bacteria rapidly without inducing cell lysis



Stage 4
R327 is rapidly and irreversibly bactericidal

# **RECCE® Multiple Anti-Infective Applications**



- 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
- Cooperative Research and Development Agreement signed with US Army Medical Research Institute of Infectious Diseases, to test R327 against biothreat pathogens in established in vitro models.

## Efficacy - RECCE® 327

- Achieved a 93% positive clinical response in diabetic foot infection (DFI) patients during Phase II trials, with no serious adverse events reported
- Multiple SAS Category A patient cases in Australia have shown rapid clinical improvement with RECCE® 327 Topical Gel, including the avoidance of surgical intervention in severe infections
- In SAS Category A use, R327 demonstrated visible reductions in swelling, redness, and infection progression within 24-72 hours of a single application
- · Maintains potency across both Gram-positive and Gram-negative bacteria, including their drug-resistant variants
- Time-kill studies show RECCE® 327 acts faster than conventional antibiotics, rapidly depleting bacterial ATP and causing irreversible bacterial death
- · Demonstrated 99.9% in vitro efficacy against the full suite of ESKAPEE pathogens

## Safety - RECCE® 327

- R327 has been shown to be safe and well tolerated across multiple Phase I and II clinical trials and/or SAS Category A
  patient cases as either intravenous or topical gel
- Phase I trials demonstrated intravenous safety profile even at high doses up to 6,000 mg delivered over a one-hour infusion
- · No clinically significant changes were observed in laboratory tests, EKGs, telemetry, or vital signs, supporting systemic safety
- · R327 displayed a clear therapeutic window across multiple dosing schedules and concentrations
- Topical application has shown to be non-irritating and well tolerated, even in infected, open wound sites
- Multiple R327 studies of mutagenicity (cancer) are clear



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