

FACT SHEET

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



APRIL 2024

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 antibiotic-resistant superbugs.

Recce's anti-infective pipeline includes three patented, broad-spectrum, synthetic polymer anti-infectives: **RECCE® 327** as an intravenous and topical therapy that is being developed for the treatment of serious and potentially life-threatening infections due to Gram-positive and Gram-negative bacteria including their superbug forms; **RECCE® 435** as an orally-administered therapy for bacterial infections; and **RECCE® 529** for viral infections. Through their multi-layered mechanisms of action, Recce's anti-infectives have the potential to overcome the hypercellular mutation of bacteria - the challenge of all existing antibiotics to date.

Sepsis affects **50 million people worldwide** a year. There are currently **no drug therapies** specifically for the treatment of severe sepsis and it is by far the **most expensive condition** treated in US hospitals.

The FDA has awarded RECCE® 327 **Qualified Infectious Disease Product** designation under the Generating Antibiotic Initiatives Now (GAIN) Act - labelling it for Fast Track Designation, plus 10 years of market exclusivity post approval. Further to this designation, RECCE® 327 has also been included on **The Pew Charitable Trusts Global New Antibiotics in Development Pipeline as the only synthetic polymer and sepsis drug candidate in development.**

Recce wholly owns its automated manufacturing, ready to support human clinical trials. Recce's anti-infective pipeline seeks to exploit the unique capabilities of RECCE® technologies targeting synergistic, unmet medical needs.

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, Diabetic Foot Infections and more**
- R327 bactericidal activity against all six ESKAPE pathogens
- Unique Mechanism of Action - R327 does not succumb to antimicrobial mutation (superbugs) - fundamental challenge of all existing antibiotics to date. It works fast and keeps on working with repeated use
- R327 cleared for use under Therapeutic Goods Administration (TGA) Special Access Scheme - Category A
- R327 included in **The Pew Charitable Trusts Global New Antibiotics in Development Pipeline as the only synthetic polymer and sepsis drug candidate in development**
- Manufacturing Established - quality and quantity suitable for all clinical trial phases (highly economic & scalable)
- Australian Government awarded **AUD \$54,947,284 (USD \$37,043,433)** Advanced Overseas Finding* across RCE infectious disease portfolio*

*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

SNAP SHOT

Ticker	ASX:RCE, FSE:R9Q
Date listed	January 2016, March 2021
52 week range	AUD \$0.4100 - A\$0.7772
Market Cap	AUD \$90.647m (priced at \$0.44)
Cash balance	A\$4m* (April 2024)
Shares on issue	203.7m
3 month avg. vol	135.96K (per trading day)
Sector	Pharmaceuticals, Biotechnology & Life Sciences

*Before 43.5% R&D Rebate submitted-net benefit from anticipated receipt during present quarter. AUD \$11,178,965 received as an R&D Advance with Endpoints Capital capturing Recce's R&D Tax incentive for FY23/24 & FY25.

BOARD AND MANAGEMENT

Dr John Prendergast	Executive Chairman
James Graham	Managing Director & Chief Executive Officer
Michele Dilizia	Executive Director & Chief Scientific Officer
Dr Justin Ward	Executive Director & Principal Quality Chemist
Dr Alan W Dunton	Chief 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	✓	2037	✓	2037
USA	✓	2029	✓	2037	✓	2037
Europe	✓	2028	✓	2037	✓	2037
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
China	✓	2028	Pending	2037	✓	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 Granted, other Patent Cooperation Treaty countries pending/allowed)

Efficacy - RECCE® 327

- 99.9% effective against full suite of ESKAPE pathogens including Multidrug-Resistant forms
- Acts against bacteria in both normal and mutated superbug forms
- Multiple tests demonstrate efficacy against Gram-positive and Gram-negative including their superbug forms
- *In-vitro* studies of RECCE® 327 demonstrate a faster kill rate than existing antibiotics
- Contains a patented polymeric structure, intentionally designed to overcome the traditional challenges of bacterial mutation/resistance
- *In-vivo* studies against SARS-CoV-2 (COVID-19) and influenza virus

Safety - RECCE® 327

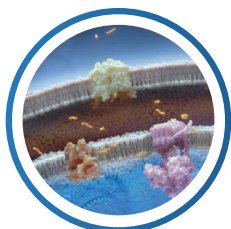
- Multiple studies of toxicity in small and large animals
- Multiple studies of mutagenicity (cancer) are clear
- Numerous studies to date indicate the safety of RECCE® 327
- Is suited to administration against sepsis by intravenous drip
- Indicates a safe therapeutic dosing window over a 1-hour infusion
- Data review of Phase I (I.V.) clinical trial of R327 in 80 human subjects, achieved all study end-points and **showed RECCE® 327 to be safe & well tolerated - no serious adverse events noted**

RECCE® 327 Mechanism of Action



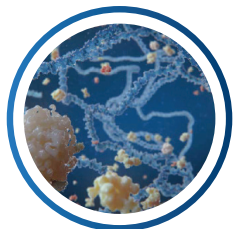
Stage 1

R327 permeabilises cell membrane and enters the cell



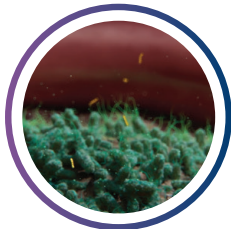
Stage 2

R327 interrupts bacterial cellular energetics via ATP Synthesis



Stage 3

Cellular division & non-dividing cell functions are disrupted



Stage 4

R327 is rapidly and irreversibly bactericidal

RECCE® Multiple Anti-Infective Applications

Asset and Route of Administration	Study name	Indications	Discovery	Pre-clinical	Phase I	Phase II	Phase III	Market
R327 Intravenous	R327-001	Serious/life threatening bacterial infections including sepsis	[Progress bar]					
	R327-002	Multidose, early stage, rapid infusions sepsis efficacy study	[Progress bar]					
	R327-003	Urinary tract infections including urosepsis	[Progress bar]					
R327 Topical	R327-101	Diabetic Foot Infections	[Progress bar]					
	R327-102	Wound infections including infected burns - post operative infection	[Progress bar]					
Pre-Clinical Programs* Various routes of administration	AIR-001	<i>Mycobacterium abscessus</i>	[Progress bar]					
	AIR-002	Bacterial Sinusitis	[Progress bar]					
	AIR-003	Additional TBA	[Progress bar]					
	AIR-004	<i>Neisseria gonorrhoeae</i>	[Progress bar]					

World Health Organisation (WHO) List of Most Threatening Antibiotic-Resistant Bacteria

The WHO published a priority list of 12 antibiotic-resistant bacteria*.

PRIORITY 1: CRITICAL	RECCE® 327
<i>Pseudomonas aeruginosa</i> , carbapenem-resistant	✓ 1
<i>Enterobacteriaceae</i> , carbapenem-resistant, ESBL-producing	✓ 2
<i>Acinetobacter baumannii</i> , carbapenem-resistant	✓ 3
PRIORITY 2: HIGH	
<i>Enterococcus faecium</i> , vancomycin-resistant	✓ 4
<i>Staphylococcus aureus</i> , methicillin-resistant, vancomycin-intermediate and resistant	✓ 5
<i>Helicobacter pylori</i> , clarithromycin-resistant	✓ 6
<i>Neisseria gonorrhoeae</i> , cephalosporin-resistant, fluoroquinolone-resistant	✓ 7
<i>Campylobacter spp.</i> , fluoroquinolone-resistant	NOT TESTED
<i>Salmonellae</i> , fluoroquinolone-resistant	NOT TESTED
PRIORITY 3: MEDIUM	
<i>Streptococcus pneumoniae</i> , penicillin-non-susceptible	✓ 8
<i>Haemophilus influenzae</i> , ampicillin-resistant	NOT TESTED
<i>Shigella spp.</i> , fluoroquinolone-resistant	NOT TESTED

- 1 Active *in vitro* against Recce's own superbug of this bacterium
- 2 Active *in vivo* against a member of this family CRE *E. coli*
- 3 Active *in vitro* and against superbug variant CRAB
- 4 Active *in vitro* against a very closely related species, *Enterococcus faecalis*
- 5 Active both *in vitro* and *in vivo* against MRSA, Methicillin-resistant *S. aureus*
- 6 Active both *in vitro* and *in vivo* against three strains (2 of which were superbugs)
- 7 Active *in vitro* (superbug not available)
- 8 Active *in vitro* against related superbug *Klebsiella pneumoniae*

* List as of 2017



Sydney – Head Office

Level 23, 180 George St
Salesforce Tower
Sydney NSW 2000
Australia

Macquarie Park – Production

Unit 8, 64 Talvera Road
Macquarie Park NSW 2113
Australia

Perth – R&D Centre

Suite 10, 3 Brodie Hall Drive
Technology Park
Bentley WA 6102
Australia

North America – Operations

Suite 1025
1717 Pennsylvania Avenue
Washington DC 20006
USA