

# FACT SHEET

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



NOVEMBER 2023

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

Recce Pharmaceuticals Ltd (ASX:RCE, FSE:R9Q) is an Australian based globally-focussed, 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** 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)

## SNAP SHOT

|                  |  |
|------------------|--|
| Ticker           | ASX:RCE, FSE:R9Q                               |
| Date listed      | January 2016, March 2021                       |
| 52 week range    | AUD \$0.4150 – A\$0.7850                       |
| Market Cap       | AUD \$92.57m (priced at \$0.45)                |
| Cash balance     | A\$8.36m* (October 2023)                       |
| Shares on issue  | 203.45m  |
| 3 month avg. vol | 262.13K (per trading day)                      |
| Sector           | Pharmaceuticals, Biotechnology & Life Sciences |

\*Before 43.5% R&D Rebate submitted-net benefit from anticipated receipt during present quarter. Figures as of 20 October 2023.

## 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    | 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

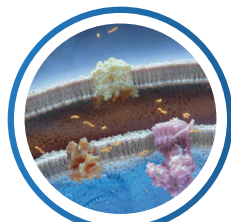
- Multiple studies of toxicity in small and large animals
- Multiple studies of mutagenicity (cancer) are clear
- Numerous studies to date indicate the safety of RECCE® 327
- Is suited to administration against sepsis by intravenous drip
- Indicates a safe therapeutic dosing window
- Data review of Phase 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



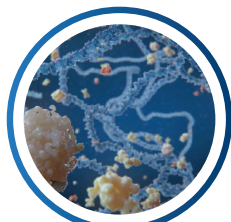
Stage 1

R327 permeabilises cell membrane and enters the cell



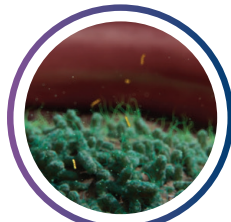
Stage 2

R327 interrupts bacterial cellular energetics via ATP Synthase



Stage 3

Cellular division & non-dividing cell functions are disrupted



Stage 4

R327 is rapidly and irreversibly bactericidal

## 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

## 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: Discovery to Phase I]        |              |         |          |           |        |
|   | R327-002   | Multidose, early stage, rapid infusions sepsis efficacy study  | [Progress bar: Discovery to Phase II]       |              |         |          |           |        |
|   | R327-003   | Urinary tract infections including urosepsis                   | [Progress bar: Discovery to Phase II]       |              |         |          |           |        |
| R327 Topical  | R327G-101  | Wound infections including infected burns                      | [Progress bar: Stage 1 - Complete, Stage 2] |              |         |          |           |        |
|   | R327-102   | Diabetic Foot Ulcer Infections                                 | [Progress bar: Discovery to Phase II]       |              |         |          |           |        |
| Pre-Clinical Programs* Various routes of administration | AIR-001    | <i>Mycobacterium abscessus</i>                                 | [Progress bar: Discovery to Pre-clinical]   |              |         |          |           |        |
|   | AIR-002    | Bacterial Sinusitis  | [Progress bar: Discovery to Pre-clinical]   |              |         |          |           |        |
|   | AIR-003    | Additional TBA   | [Progress bar: Discovery to Pre-clinical]   |              |         |          |           |        |



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