# Recce Pharmaceuticals

**RCE.AX**

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27 June 2024

# Ethics Approval for Wider Trial of R327 Gel – Many Unmet Needs

## NEED TO KNOW

- Human Research Ethics Committee (HREC) approves Phase 2 clinical trial for R327 Gel in a large range of indications
- Higher chance to demonstrate efficacy against a broader array of bacteria; US$26 bn opportunity by 2032
- WHO inclusion also raises the profile of R327

**Human Research Ethics Committee (HREC) has approved the Phase 2 trial which is commencing soon:** The approval covers a trial of RECCE® 327 (R327) Gel as a topical, broad-spectrum treatment for a broad range of bacterial skin infections categorised as Acute Bacterial Skin and Skin Structure Infections (ABSSSIs). First patients will be dosed in 3QCY24.

**Benefits – wider goal posts mean more chance to show efficacy:** The ABSSSIs category unifies diverse infections (DFIs, post-surgical) with high unmet needs. R327's prior success in burns and DFIs informs this broader trial, potentially demonstrating efficacy against a wider range of bacteria.

**Substantial business opportunity from a growing market:** The ABSSSI treatment market (2018 value of US$7.3 bn) is projected to grow at a 9.5% CAGR to 2032. The growing problem of antimicrobial resistance and a lack of treatments for Gram-negative pathogens represent major unmet needs.

**WHO inclusion for R327 raises profile:** The WHO has included R327 in a report on developing antibiotics – the only drug in its category. This lifts R327's profile, possibly helping attract licensees/development partners in the future.

## Investment Thesis

**Developing a new anti-infective class for hard-to-treat infections:** Recce leverages Dr. Melrose's novel acrolein polymer technology to develop novel synthetic anti-infectives targeting difficult-to-treat, multi-drug resistant bacteria and viruses.

**Novel mechanism of action (MOA):** R327 exhibits novel in-vitro MOA, remaining water-soluble across all pH levels, including the human stomach.

**Fighting back against antimicrobial resistance – even superbugs:** R327 is a novel, broad-spectrum anti-infective that is designed to overcome antimicrobial resistance, including superbug forms, even after repeated use.

**Substantial promise in preclinical testing:** R327 has shown significant selective interaction with a broad range of bacterial cells and viruses in preclinical testing to date.

## Valuation/Risks

Our A$2.46/share valuation (unchanged) is calculated using a risk-adjusted net present value method. Recce is subject to various risks typically associated with biotech companies in the early stages of drug development, including the possibility of unfavourable outcomes in clinical trials.


**Equity Research Australia**

**Pharmaceuticals, Biotechnology/Life Sciences**

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Recce Pharmaceuticals

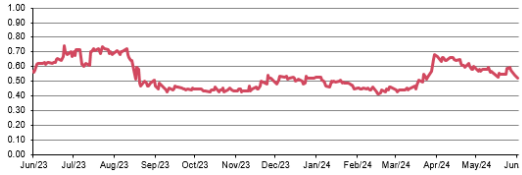
Recce Pharmaceuticals is a clinical-stage biopharmaceutical company which is developing and commercialising a new class of synthetic anti-infectives to address antibiotic-resistant bacteria (superbugs) and emerging viral pathogens. Patented lead candidate RECCE® 327 (R327) is being developed in a variety of formulations to treat potentially life-threatening infections including sepsis due to Gram-positive and Gram-negative bacteria including superbug forms. R327 is on the Pew Charitable Trust's Global New Antibiotics in Development Pipeline as the only synthetic polymer and sepsis drug candidate in development. www.recce.com.au

| | |
|---|---|
| Valuation | **A$2.46** *(unchanged)* |
| Current price | **A$0.52** |
| Market cap | **A$106m** |
| Cash on hand | **$8.5m** *(as at 31 March 2024)* |

### Upcoming Catalysts / Next News

| Period | |
|---|---|
| 3QCY24 | Phase1/2 trial interim data: UTI |
| 3QCY24 | Phase 2 trial commencement |
| | bacterial skin & soft tissue post-op |
| 3QCY24 | Phase 3 registrational trial: |
| | DFI (Indonesia) |
| 2HCY24 | FDA submission of IND for R327(IV) |
| 2HCY24 | Grant funding from the U.S. DOD |

### Share Price (A$)





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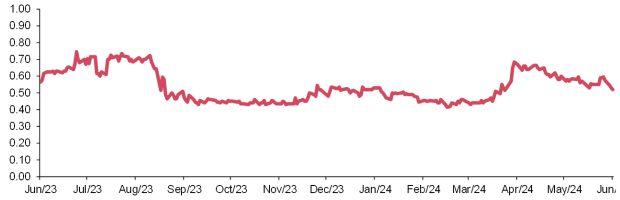
## Recce Pharmaceuticals — RCE-AU

**Year end 30 June, AUD unless otherwise noted**

### MARKET DATA

| | | |
|---|---|---|
| **Price** | **$** | **0.52** |
| 52 week high / low | $ | 0.42-0.75 |
| **Valuation** | **$** | **2.46** |
| Market capitalisation | $m | 105.8 |
| **Shares on issue (basic)** | **m** | 203.5 |
| Options / rights | m | 14.3 |
| Other equity | m | 0.0 |
| **Shares on issue (diluted)** | **m** | **217.8** |

### 12-MONTH SHARE PRICE PERFORMANCE (A$)




| INVESTMENT FUNDAMENTALS | | FY22A | FY23A | FY24E | FY25E | FY26E |
|---|---|---|---|---|---|---|
| Reported NPAT | $m | (11.0) | (13.1) | (12.5) | (8.4) | (9.6) |
| **Underlying NPAT** | **$m** | **(11.0)** | **(13.1)** | **(12.5)** | **(8.4)** | **(9.6)** |
| Reported EPS (diluted) | ¢ | (6.3) | (7.5) | (7.0) | (4.1) | (4.2) |
| **EPS Underlying (diluted)** | **¢** | **(6.3)** | **(7.5)** | **(7.0)** | **(4.1)** | **(4.2)** |
| Growth | % | | | | | |
| **Underlying PER** | **x** | **nm** | **nm** | **nm** | **nm** | **nm** |
| Operating cash flow per share | ¢ | -5.2 | -7.3 | -7.0 | -4.1 | -4.2 |
| Free cash flow per share | ¢ | -5.2 | -7.3 | -7.0 | -4.1 | -4.2 |
| **Price to free cash flow per share** | **x** | **nm** | **nm** | **nm** | **nm** | **nm** |
| FCF Yield | % | nm | nm | nm | nm | nm |
| **Dividend** | **¢** | **0.0** | **0.0** | **0.0** | **0.0** | **0.0** |
| Payout | % | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% |
| **Yield** | **%** | **0.0%** | **0.0%** | **0.0%** | **0.0%** | **0.0%** |
| Franking | % | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% |
| **Enterprise value** | **$m** | **94.3** | **104.5** | **106.0** | **102.3** | **101.9** |
| EV/EBITDA | x | (8.5) | (8.0) | (8.5) | (12.3) | (10.6) |
| EV/EBIT | x | (8.5) | (7.9) | (8.5) | (12.3) | (10.6) |
| Price to book (NAV) | x | 5.5 | (27.3) | (22.2) | (215.5) | (1,576.3) |
| Price to NTA | x | 5.5 | (27.3) | (22.2) | (215.5) | (1,576.3) |

| KEY RATIOS | | FY22A | FY23A | FY24E | FY25E | FY26E |
|---|---|---|---|---|---|---|
| EBITDA margin | % | nm | nm | nm | nm | nm |
| EBIT margin | % | nm | nm | nm | nm | nm |
| NPAT margin | % | nm | nm | nm | nm | nm |
| ROE | % | nm | nm | nm | nm | nm |
| ROA | % | nm | nm | nm | nm | nm |
| Net tangible assets per share | $ | 0.1 | (0.0) | (0.0) | (0.0) | (0.0) |
| Book value per share | $ | 0.1 | (0.0) | (0.0) | (0.0) | (0.0) |
| Net debt/(cash) | $m | (11.5) | (1.3) | 0.2 | (3.5) | (3.9) |
| Interest cover/ (EBIT/net interest) | x | nm | nm | nm | nm | nm |
| Gearing (net debt/EBITDA) | x | nm | nm | (0.0) | nm | nm |
| Leverage (net debt/(net debt + equit | x | nm | nm | (0.0) | nm | nm |

| DUPONT ANALYSIS | | FY22A | FY23A | FY24E | FY25E | FY26E |
|---|---|---|---|---|---|---|
| Net Profit Margin | % | nm | nm | nm | nm | nm |
| Asset Turnover | x | nm | nm | nm | nm | nm |
| Return on Assets | % | nm | nm | nm | nm | nm |
| Leverage | x | nm | nm | nm | nm | nm |
| **Return on Equity** | % | nm | nm | nm | nm | nm |

### Clinical development pipeline

| Anti-bacterial programs | Indication | Status |
|---|---|---|
| R327 (intravenous) | Severe sepsis -blood poisoning | Phase 1 |
| R327 (intravenous) | Urinary tract infections | Phase 1b/2a |
| R327 (topical) | Burn wound infection | Phase 1b/2a |
| R327 (topical) | Diabetic foot ulcers | Phase 1b/2a |
| R435 (oral) | *Helicobacter pylori* in stomach ulcsers | Preclinical |
| **Anti-viral programs** | **Indication** | **Status** |
| R327 (nasal) | SARS-CoV-2 & other viral infections | Preclinical |
| R529 (intravenous and nasal) | Viral infections | Preclinical |

| HALF YEARLY DATA | | 2H21 | 1H22 | 2H22 | 1H23 | 2H23 |
|---|---|---|---|---|---|---|
| Total Revenue | $m | 1.2 | 0.0 | 3.1 | 0.0 | 4.3 |
| Operating expenses | $m | (4.5) | (5.0) | (9.1) | (9.2) | (8.2) |
| EBITDA | $m | (3.3) | (5.0) | (6.0) | (9.2) | (3.9) |
| EBIT | $m | (3.4) | (5.0) | (6.0) | (9.3) | (3.9) |
| PBT | $m | (3.3) | (5.0) | (6.0) | (9.2) | (3.9) |
| **Reported NPAT** | $m | (3.3) | (5.0) | (6.0) | (9.2) | (3.9) |

| PROFIT AND LOSS | | FY22A | FY23A | FY24E | FY25E | FY26E |
|---|---|---|---|---|---|---|
| **Revenue** | **$m** | **0.0** | **0.0** | **0.0** | **0.0** | **0.0** |
| Other income | $m | 3.1 | 4.4 | 4.7 | 4.7 | 3.1 |
| **Total Revenue** | **$m** | **3.1** | **4.4** | **4.7** | **4.7** | **3.1** |
| Operating expenses | $m | (14.1) | (17.5) | (17.1) | (13.0) | (12.7) |
| **EBITDA** | **$m** | **(11.0)** | **(13.1)** | **(12.4)** | **(8.3)** | **(9.6)** |
| Depreciation & Amortisation | $m | (0.0) | (0.0) | (0.0) | (0.0) | (0.0) |
| **EBIT** | **$m** | **(11.1)** | **(13.1)** | **(12.5)** | **(8.4)** | **(9.6)** |
| Net interest | $m | 0.1 | 0.1 | 0.0 | 0.0 | 0.0 |
| **Pretax Profit** | **$m** | **(11.0)** | **(13.1)** | **(12.5)** | **(8.4)** | **(9.6)** |
| Tax expense | $m | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| **Reported NPAT** | **$m** | **(11.0)** | **(13.1)** | **(12.5)** | **(8.4)** | **(9.6)** |
| **Underlying NPAT** | $m | **(11.0)** | **(13.1)** | **(12.5)** | **(8.4)** | **(9.6)** |
| Weighted average diluted shares | m | 174.1 | 174.0 | 178.3 | 203.5 | 230.9 |
| End of year shares | | 177.6 | 178.3 | 203.5 | 230.9 | 253.8 |

| GROWTH PROFILE | | FY22A | FY23A | FY24E | FY25E | FY26E |
|---|---|---|---|---|---|---|
| Revenue | % | nm | nm | nm | nm | nm |
| EBITDA | % | nm | nm | nm | nm | nm |
| EBIT | % | nm | nm | nm | nm | nm |
| Reported NPAT | % | nm | nm | nm | nm | nm |
| DPS | % | nm | nm | nm | nm | nm |

| BALANCE SHEET | | FY22A | FY23A | FY24E | FY25E | FY26E |
|---|---|---|---|---|---|---|
| Cash | $m | 11.6 | 1.6 | 0.1 | 3.7 | 4.1 |
| Receivables | $m | 0.2 | 0.1 | 0.1 | 0.1 | 0.1 |
| Inventory | $m | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Other | $m | 0.4 | 0.3 | 0.3 | 0.3 | 0.3 |
| **Current assets** | **$m** | **12.2** | **1.9** | **0.5** | **4.1** | **4.5** |
| PPE | $m | 0.4 | 0.4 | 0.4 | 0.3 | 0.3 |
| Right-of-use assets | $m | 0.1 | 0.2 | 0.2 | 0.2 | 0.2 |
| Intangible assets | $m | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Other | $m | 0.0 | (0.0) | (0.0) | 0.0 | (0.0) |
| **Non current assets** | **$m** | **0.4** | **0.6** | **0.6** | **0.6** | **0.6** |
| **Total assets** | **$m** | **12.6** | **2.6** | **1.1** | **4.7** | **5.1** |
| Trade and other payables | $m | 0.8 | 4.3 | 4.3 | 4.3 | 4.3 |
| Borrowing and leases | $m | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 |
| Other | $m | 1.6 | 0.4 | 0.4 | 0.4 | 0.4 |
| **Current liabilities** | **$m** | **2.4** | **4.8** | **4.8** | **4.8** | **4.8** |
| Borrowing and leases | $m | 0.0 | 0.1 | 0.1 | 0.1 | 0.1 |
| Other liability | $m | 0.1 | 0.2 | 0.2 | 0.2 | 0.2 |
| **Non current liabilities** | **$m** | **0.1** | **0.3** | **0.3** | **0.3** | **0.3** |
| **Total liabilities** | **$m** | **2.6** | **5.1** | **5.1** | **5.1** | **5.1** |
| **Net assets** | **$m** | **10.1** | **(2.6)** | **(4.1)** | **(0.4)** | **(0.1)** |
| Share capital | $m | 44.0 | 44.1 | 55.1 | 67.1 | 77.1 |
| Retained earnings | $m | (42.5) | (55.5) | (68.0) | (76.4) | (86.0) |
| Other | $m | 8.6 | 8.8 | 8.8 | 8.8 | 8.8 |
| **Total equity** | **$m** | **10.1** | **(2.6)** | **(4.1)** | **(0.4)** | **(0.1)** |

| CASH FLOW | | FY22A | FY23A | FY24E | FY25E | FY26E |
|---|---|---|---|---|---|---|
| **Net loss for period** | **$m** | **(11.0)** | **(13.1)** | **(12.5)** | **(8.4)** | **(9.6)** |
| Depreciation & Amortization | $m | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Changes in working capital | $m | 1.5 | (0.2) | 0.0 | 0.0 | 0.0 |
| Other | $m | 0.4 | 0.5 | (0.0) | 0.0 | (0.0) |
| **Operating cash flow** | **$m** | **(9.0)** | **(12.7)** | **(12.4)** | **(8.3)** | **(9.6)** |
| Payments for PPE | $m | (0.0) | (0.0) | (0.0) | (0.0) | (0.0) |
| Other | $m | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| **Investing cash flow** | **$m** | **(0.0)** | **(0.0)** | **(0.0)** | **(0.0)** | **(0.0)** |
| Equity | $m | 0.0 | 0.0 | 11.0 | 12.0 | 10.0 |
| Borrowing and Lease liability net payment | $m | (0.1) | 2.7 | 0.0 | 0.0 | 0.0 |
| Other | $m | (0.1) | (0.0) | 0.0 | 0.0 | 0.0 |
| **Financing cash flow** | **$m** | **(0.2)** | **2.7** | **11.0** | **12.0** | **10.0** |
| **Cash year end** | **$m** | **11.6** | **1.6** | **0.1** | **3.7** | **4.1** |
| **Free cash flow** | **$m** | **(9.1)** | **(12.7)** | **(12.5)** | **(8.3)** | **(9.6)** |

Source: Company reports, MST Access estimates

## More information on WHO inclusion

The World Health Organization (WHO) has included R327 in its Antibacterial Agents in Clinical Development and Preclinical Development report. In our view, this will raise the drug's profile and potentially assist to attract licensees or development partners in future.

R327 is the only drug included in the WHO's 'ATP production disruptor' category. ATP is an energy-carrying molecule which captures and releases energy for use in cells. Disruption of ATP production in bacterial cells, according to Recce, 'carries the potential to confer activity against both Gram-positive and Gram-negative pathogens'.

## Risks and sensitivities

Beyond technological risk, Recce Pharmaceuticals is subject to various risks typically associated with biotech companies in the early stages of drug development, including the possibility of unfavourable outcomes in clinical trials, regulatory decisions, success of competitors, financing, and commercial risk.

- **Technology:** Recce is a pioneer in developing a new class of anti-infectives based on acrolein polymer technology with a clinical strategy targeting major unmet medical needs and markets. Despite the relative lack of new anti-infective categories emerging over the past several decades, and the rise of antimicrobial resistance in the meantime, it remains to be seen whether Recce can prove efficacy in human clinical trials with its synthetic polymer approach.
- **Clinical trials:** Technology aside, clinical risk remains significant given the early stage of clinical development and the task at hand. Developing a new antimicrobial treatment depends on multiple factors including the vulnerability of the host, virulence of the organism, and the use of antimicrobials which are both efficacious on repeated use and able to penetrate tissue in time to prevent unwanted spread. As a non-traditional synthetic compound, acquisition of resistance to Recce products may prove harder for micro-organisms, but this is yet to be established in human trials.
- **Funding risk:** The company is currently funding all clinical programs and may need to raise additional capital to support studies of new clinical targets. Any shortfall in the amount raised or underestimation of forecasted costs may add to funding risk and the ability to raise capital in the future.
- **Regulatory:** Notwithstanding gaining QIDP status in sepsis, Recce will need to gain approval from the FDA or international regulatory bodies for marketing in the US or ROW before entering the market, assuming clinical data is positive.
- **Commercialisation and reimbursement:** In the absence of a development partner, and assuming clinical development is successful and regulatory approvals achieved, the company will need to secure manufacturing at scale, quality control, marketing, and distribution of its products. Although manufacturing can be outsourced to a degree, maintaining the low cost of goods, Recce's strategy of maintaining all rights to the technology through to launch and beyond adds considerable risk to the choice of distributor and distribution strategy overall.
- **Intellectual property:** We consider intellectual property risk as low given the company's broad portfolio of patents in all key geographies. Nonetheless, given its go-it-alone commercialisation strategy, Recce may be forced to defend its intellectual property through litigation and in the absence of a partner or licensor absorb all legal costs.

# Personal disclosures

Chris Kallos, CFA received assistance from the subject company or companies in preparing this research report. The company provided them with communication with senior management and information on the company and industry. As part of due diligence, they have independently and critically reviewed the assistance and information provided by the company to form the opinions expressed in this report. They have taken care to maintain honest and fair objectivity in writing this report and making the recommendation. Where MST Financial Services or its affiliates has been commissioned to prepare content and receives fees for its preparation, please note that NO part of the fee, compensation or employee remuneration paid has, or will, directly or indirectly impact the content provided in this report.

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Recce Pharmaceuticals (RCE.AX) | Price A$0.52 | Valuation A$2.46;

*Price and valuation as at 27 June 2024 (* not covered)*

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