Recce Pharmaceuticals

RCE.AX

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08 May 2024

Global IP protection now complete

NEED TO KNOW

- Granting of Patent Family 2 by China's IP authority
- Green light for higher dose of RECCE® 327
- 3Q24 cash on hand of $8.5m

China's IP authority grants claims relating to R327, R529: The China National Intellectual Property Administration's formal grant of Patent Family 2 strengthens Recce's intellectual property (IP) portfolio, thereby solidifying the company's patent protection across all major pharmaceutical markets globally. The granted Chinese patent claims relate to RECCE® 327 and RECCE® 529, most notably methods of manufacture, administration, and application to treat a broad range of common human infections.

Independent Safety Committee approves dose escalation for R327 in the Phase 1/2 UTI/urosepsis trial: The safety committee approved a 4,000mg intravenous (IV) dose of R327 over 30 minutes. Subject recruitment is ongoing, with dosing for the first 6 participants expected soon. Prior studies at 3,000mg (various infusion times) achieved MIC activity. Based on these results, 30 minutes was chosen as the optimal time, and the dose was increased to explore higher concentration potential. The full efficacy of IV R327 will be determined upon trial completion. Notably, topical R327 in a separate program showed promise against antibiotic-resistant infections.

3Q24 results: Recce's cash position strengthened at the end of the quarter, reaching $8.5m, which includes drawdown on the A$11.2m R&D Advance from Endpoints Capital for FY23 and FY24 R&D tax rebates, compared to $4m at the end of December 2023. Operating activities resulted in net cash outflows of $4.7m. The primary driver of these outflows was research and development (R&D) at $3.6m, supporting ongoing human clinical trials and pre-clinical studies. The remaining outflow of $0.7m went towards payments to related parties, such as executive and director fees.

Investment Thesis

Developing a new class of anti-infectives for hard-to-treat infections: Recce is developing synthetic polymer anti-infective agents for bacterial and viral infections that are difficult to treat with existing medications. Its agents are based on the proprietary and novel acrolein polymer technology developed by Recce's founder and inventor, Dr Graham Melrose.

Novel mechanism of action (MOA): R327 shows a novel MOA in *in-vitro* testing. It is water-soluble at all pH levels, including that of 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 is unchanged and is calculated using a risk-adjusted net present value method. RCE 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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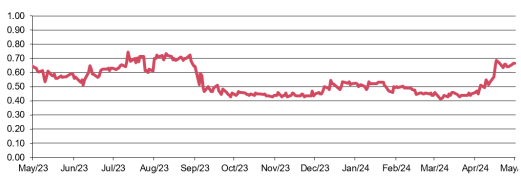
Recce Pharmaceuticals is a clinical-stage biopharmaceutical company which is developing and commercialising a new class of synthetic anti-infectives to address antibiotic-resistant bacteria (superbugs) and emerging viral pathogens. Patented lead candidate RECCE® 327 (R327) is being developed in a variety 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$0.67**
Market cap	**A$133m**
Cash on hand	**A$8.5m** *(31 March 2024)*

Upcoming Catalysts / Next News

Period	
2QCY2	Phase I/II UTI trial interim update
2QCY24	Phase I/II DFI trial interim update
3QCY24	Phase III reg. trial for DFI (Indonesia)
2HCY24	FDA submission of IND for R327 (IV)
2HCY24	Grant funding from US DOD

Share Price (A$)



Source: FactSet, MST Access

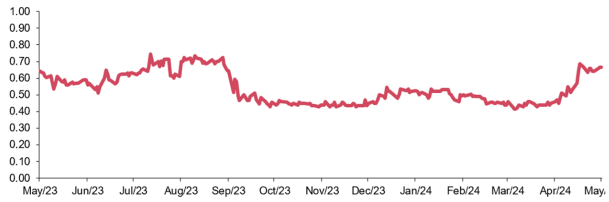
Recce Pharmaceuticals — RCE-AU

Year end 30 June, AUD unless otherwise noted

MARKET DATA

Price	**$**	**0.67**
52 week high / low	$	0.42-0.75
Valuation	**$**	**2.46**
Market capitalisation	$m	135.3
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)
Underlying EPS (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**	**123.8**	**134.0**	**135.5**	**131.8**	**131.4**
EV/EBITDA	x	(11.2)	(10.2)	(10.9)	(15.9)	(13.7)
EV/EBIT	x	(11.2)	(10.2)	(10.8)	(15.8)	(13.6)
Price to book (NAV)	x	7.1	(35.0)	(28.3)	(275.5)	(2,015.9)
Price to NTA	x	7.1	(35.0)	(28.3)	(275.5)	(2,015.9)

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 + equity))	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	0.2	1.7	4.4	1.0	0.6
Return on Assets	%	nm	nm	nm	nm	nm
Leverage	x	1.3	(1.0)	(0.3)	(11.0)	(86.5)
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)**
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	%	66.1	41.5	7.4	0.0	(33.3)
EBITDA	%	(18.3)	18.7	(4.9)	(33.3)	15.4
EBIT	%	(18.7)	18.7	(4.9)	(33.2)	15.3
Reported NPAT	%	(18.7)	19.0	(4.5)	(33.1)	15.3
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 payments	$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

3Q24: Operational highlights

Clinical progress

Phase 1/2 clinical trial for diabetic foot infection treatment

Positive human efficacy data to support site expansion ongoing

Recce's Phase 1/2 clinical trial for topical R327 against diabetic foot infections (DFIs) achieved its primary goals, successfully resolving/curing bacterial infections. Building on this success, Recce plans to expand clinical sites domestically and internationally, aiming to accelerate patient recruitment and broaden the study population. This interventional trial assessed R327's safety and efficacy for DFI treatment, with patients receiving daily or bi-daily topical application for 14 days.

Independent Safety Committee approves expansion

Recce announced that an Independent Safety Committee has unanimously agreed the study is meeting its primary endpoints and recommended expansion based on successful treatment outcomes. To provide broader patient access, the trial will now encompass a wider range of DFI severity and infection stages at the Liverpool Hospital NSW, managed by the Ingham Institute.

Phase 1/2 UTI/urosepsis rapid infusion clinical trial

Dosing completed in next cohort

Recce successfully dosed another group of participants in its Phase 1/2 clinical trial for UTI/urosepsis with R327. This cohort received 3,000mg of the drug intravenously over a 20-minute infusion. The company is currently investigating various infusion times (15, 20, 30 and 45 minutes, and 1 hour) at the same dosage to determine the optimal dosing regimen.

Positive results from recent urine sample analysis in pre-clinical studies suggest that R327 delivered through fast infusion has the potential to combat bacteria in urine relevant to UTI/urosepsis. Recce recently received safety committee approval to increase the dosage of R327 to 4,000mg over 30 minutes in its ongoing Phase 1/2 clinical trial. This represents the highest dosage tested yet in this trial and is expected to begin shortly.

Strategic initiatives

Strategic partnership in South-East Asia to accelerate clinical program

During the quarter, Recce announced the signing of a Memorandum of Understanding (MoU) with PT Etana Biotechnologies (Etana), a leading Indonesian biomedical organisation. This partnership aims to expedite clinical development of Recce's anti-infective portfolio across Indonesia.

Notably, Indonesia faces a critical diabetes challenge, with 10.8% of adults affected – one of the world's highest rates. Nearly a third of these diabetics develop diabetic foot ulcers (DFUs) in their lifetime, and half of those ulcers become infected. These DFU infections are particularly concerning as up to 20% can lead to amputation.

Strategic partnership with Murdoch Children’s Research Institute

The Murdoch Children's Research Institute (MCRI) continues to host Recce's dedicated Anti-Infective Research (AIR) Unit. Established in 2023, this unit represents an important and ongoing collaboration between both entities in anti-infective therapy research.

Investigational New Drug application with the US FDA expected in 2HCY24 for US trial initiation in 1HCY25

On 8 April, Recce announced a significant step forward in its development plans. The company intends to submit an Investigational New Drug (IND) application to the US Food and Drug Administration (FDA) in 2HCY24. This application, if successful, would pave the way for the initiation of clinical trials in the United States during 1HCY25.

US Department of Defence

The US Department of Defence has recommended R327 Gel (R327G) for grant funding of $2.2m (A$3.34m) as a potential topical treatment for burn wound infections. This funding would accelerate the development and evaluation of R327G's ability to rapidly resolve infections and minimise complications, such as sepsis, in burn patients.

Sensitivities and Risks

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 anti-microbial 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$0.67 | Valuation A$2.46;

Price and valuation as at 08 May 2024 (not covered)*

Additional disclosures

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