Recce Pharmaceuticals

RCE.AX

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19 October 2023

Faster infusion rate well tolerated in clinical trial; strong capital raise

NEED TO KNOW

- Cohort dosing complete for Phase 1/2 UTI/urosepsis clinical trial – faster infusion rate well tolerated
- Capital raising of A$11m sees strong support from sophisticated and institutional investors – funds for clinical trials, preclinical portfolio, manufacturing

Faster infusion rate of R327 well tolerated in UTI/urosepsis clinical trial as next cohort being recruited: Recce Pharmaceuticals has announced the successful completion of cohort dosing for its Phase 1b/2a UTI/urosepsis trial which is evaluating faster infusion (intravascular) rates for lead candidate RECCE® 327 (R327). The study has shown R327 was well tolerated at a faster infusion rate of 3,000mg in 30 minutes. An Independent Safety Committee is reviewing the complete data, and recruitment has commenced for the next cohort.

Placement and entitlement offer strongly supported: The capital raising of A$11m (before costs) included:

- a **placement** which raised A$8.0m (18.2m new ordinary shares at A$0.44/share; participants included a FIL that now has a >5% stake)
- an **entitlement offer** which raised A$3.0m (eligible shareholders offered 1 new share for every 26 held at same price of A$0.44/share; participants included Recce directors).

Capital raising creates runway for key strategic objectives: Recce proposes to use the funds as follows: clinical trials (A$6m), buildout of advanced preclinical portfolio (A$2m), boosting manufacturing including geographical expansion into USA ($1m), and general working capital (A$2m).

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

Our A$2.46/share valuation (prev. A$2.77), is calculated using a risk-adjusted net present value method and shares on issue of 203.5m (post capital raise).

Risks

Beyond technological risk, our valuation 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.

Equities Research Australia

Pharmaceuticals, Biotechnology and 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.

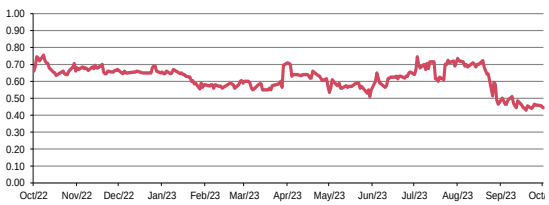
https://www.recce.com.au

Valuation	**A$2.46** *(Prev. A$2.77)*
Current price	**A$0.45**
Market cap	**A$91m**
Cash on hand	**A$12.6m** *(5 October 2023, includes $11m capital raise (before costs))*

Upcoming Catalysts/Newsflow

2HCY23	Readouts for rapid IV infusion study
2HCY23	Initiate Phase 2 sepsis trial
4QCY23	Interim readouts for Phase 1/2 DFI study
4QCY23	Phase 1/2 burn wound infection trial readout

Share Price (A$)



Source: FactSet, MST Access.

Financial Summary

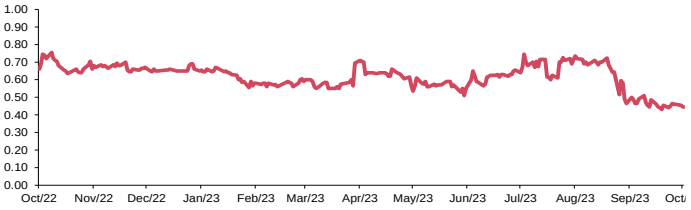
Recce Pharmaceuticals — RCE-AU

Year end 30 June, AUD unless otherwise noted

MARKET DATA

Price	**$**	**0.45**
52 week high / low	$	0.43-0.76
Valuation	**$**	**2.46**
Market capitalisation	$m	90.5
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%	100.0%	200.0%	300.0%	400.0%
Enterprise value	**$m**	**79.0**	**89.2**	**90.7**	**87.0**	**86.7**
EV/EBITDA	x	(7.2)	(6.8)	(7.3)	(10.5)	(9.0)
EV/EBIT	x	(7.1)	(6.8)	(7.3)	(10.4)	(9.0)
Price to book (NAV)	x	4.7	(23.4)	(19.0)	(184.4)	(1349.0)
Price to NTA	x	4.7	(23.4)	(19.0)	(184.4)	(1,349.0)

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)

Source: Company reports, MST Access estimates

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)**

Successful $11m raise with R&D rebates provides a 12-month runway

Recce has raised a total of $11m (before costs) at $0.44 per share, comprising a $8m share placement and a $3m entitlement offer.

Capital raised will be used to fund various clinical trials and provide general working capital. Recce proposes to use the funds as follows: clinical trials (A$6m), buildout of advanced preclinical portfolio (A$2m), boosting manufacturing including geographical expansion into USA ($1m), and general working capital (A$2m).

Figure 1: Recce clinical pipeline (multiple indications at various stages of development)

Source: Recce Pharmaceuticals.

Clinical trials update

Intravenous

Phase I I.V. Clinical Trial (ACTRN12621001313820)

This trial is an 80-patient Phase 1 trial evaluating the safety and tolerability of the intravenous infusion of R327 as a single ascending dose. It is being conducted at CMAX Clinical Research.

Dosing has been completed, with a total of 80 healthy subjects intravenously dosed (60 with R327 and 20 with placebo) to evaluate the safety and pharmacokinetics of R327.

After dosing 8 cohorts of patients, a dose ceiling of 6,000mg was established (a 120-fold increase on the commencing dose of 50mg in the first cohort), with no serious adverse events being observed.

As such, the Phase 1 study met all primary endpoints and was approved by the HREC (Human Research Ethics Committees) for evaluation at faster infusion rates in both male and female healthy subjects.

Phase 1/2 Rapid Infusion UTI/Urosepsis I.V. Clinical Trial (ACTRN12623000448640)

Recce has since announced the successful completion of cohort dosing for its Phase 1b/2a UTI/urosepsis trial which is evaluating faster infusion (intravascular) rates for R327. The study has shown R327 was well tolerated at a faster infusion rate of 3,000mg in 30 minutes. An Independent Safety Committee is reviewing the complete data, and recruitment has commenced for the next cohort.

Notably, the trial has expanded its clinical trial sites to multiple states, including CMAX Clinical Research (South Australia) and Scientia Clinical Research (New South Wales), allowing the study to be expedited and to broaden the patient population across multiple facilities.

Topical

Phase I/II Topical Diabetic Foot Infection Clinical Trial (ACTRN12623000056695)

Recce has announced that patient dosing has commenced for its 14-day Phase 1/2 proof-of-concept study of R327 as a diabetic foot infection (DFI) treatment. The 32-patient trial will evaluate the topical use of R327 as a broad-spectrum anti-infective treatment for mild skin and soft tissue DFIs and assess its efficacy and tolerability.

The clinical trial is being conducted at Liverpool Hospital's South West Sydney Limb Preservation and Wound Research Unit. Patients will be dosed daily over 14 days with topical R327 by out-patient (at-home) nurses. The study aims to capture a broad patient pool while ensuring that treatment protocols are adhered to and will consider the drug's ease of use as a topical application.

Recce has indicated that interim readouts on the study will be released later in 4QCY23.

Phase I/II Topical Burn Wound Infection Clinical Trial (ACTRN12621000412831)

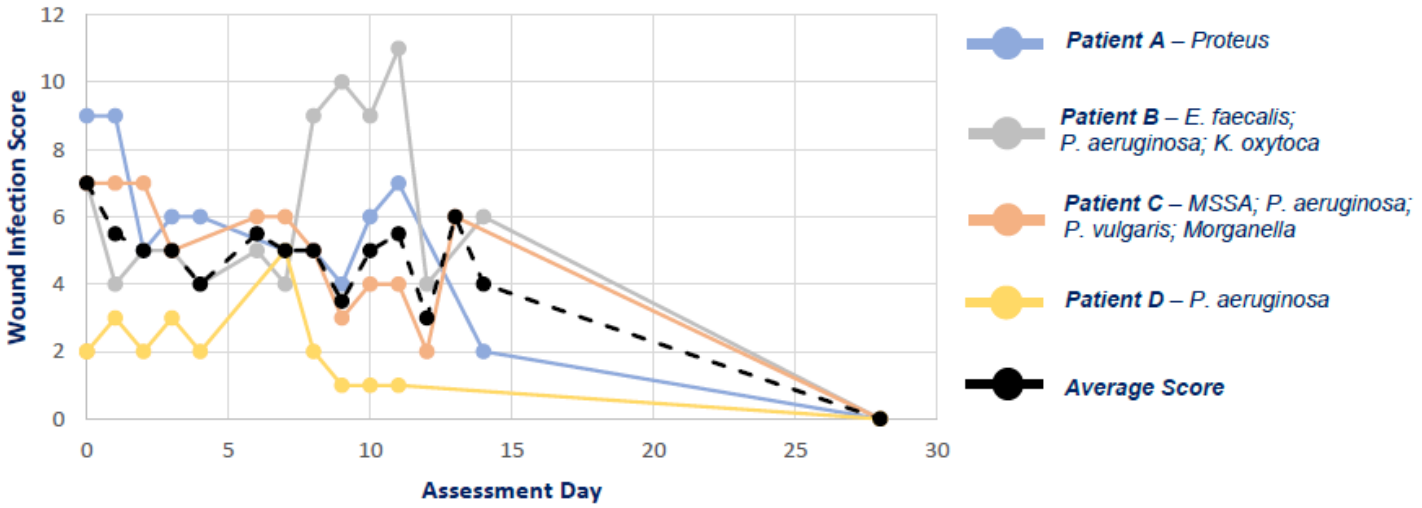
The 30-patient Phase 1/2 proof-of-concept study is evaluating R327 as a spray-on, broad-spectrum antibiotic for the treatment of topical burn wound infections.

The trial includes patients exhibiting multiple bacterial species in and surrounding the wound. These include pathogens from the ESKAPE group of bacteria (Gram-negative pathogens considered to be of 'critical priority' by the World Health Organization).

All patients treated with R327 have shown good indications of safety and tolerability to the compound. Clinicians have reported encouraging signs of improvement within 24 hours following treatment with R327, including:

- healthy skin growth
- reduced swelling
- reduced infection
- indication of tissue penetration to the side of the underlying infection.

Figure 2: Patient wound scores with associated bacterial cultures



Source: Recce Pharmaceuticals.

Difficulties in recruitment for the study (due to the implementation of the COVID protocols at the Fiona Stanley Hospital Burns Unit in WA) led to patients not meeting protocol requirements, which included no prior antibiotic treatment prior to enrolment.

Recce is working to expand the number of Australian and international clinical sites and expects to announce progress in FY2024.

As such, clinical investigators are currently preparing a new protocol, in line with the study's stated objective to progress to the next stage: a 'head-to-head' investigation of R327G and the existing standard of care.

Preclinical program update

Recce has established an Anti-Infective Research Unit located within the Murdoch Children's Research Institute to focus on advancing studies of R327 in indications such as *Mycobacterium abscessus* and bacterial sinusitis.

Methodology & Disclosures

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