

Recce Pharmaceuticals

Quarterly update

Advances on several fronts

Healthcare

Recce Pharmaceuticals has reported several encouraging developments in recent weeks for its lead development compound RECCE® 327 (R327). The intravenous (IV) R327 formulation is advancing to a higher dose level (4,000mg) in its ongoing Phase I/II rapid infusion study and the company is progressing in its plan to submit a US Investigational New Drug (IND) application to commence a US Phase II complicated urinary tract infection (cUTI) study before end-CY24. Recce is also planning to start an Indonesian Phase III registrational study in Q3 CY24, which we anticipate could lead to initial commercialisation in South-East Asia in H2 CY26. We have made minor adjustments to our valuation and now obtain a risk-adjusted net present value (rNPV) of A\$661.3m (or A\$3.27/share), versus A\$644.4m previously.

Year end	Revenue (A\$m)	PBT* (A\$m)	EPS* (A\$)	DPS (A\$)	P/E (x)	Yield (%)
06/22	3.1	(11.0)	(0.06)	0.0	N/A	N/A
06/23	4.3	(13.1)	(0.08)	0.0	N/A	N/A
06/24e	9.2	(14.6)	(0.08)	0.0	N/A	N/A
06/25e	6.7	(58.3)	(0.29)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

IND filing for IV R327 planned for H2 CY24

Recce's ongoing Phase I/II rapid infusion IV R327 study in healthy volunteers is progressing well, with the company successfully dosing 3,000mg in study cohorts at multiple infusion times down to 15 minutes. Recce received clearance to include a cohort that will receive [4,000mg of R327 dosed over 30 minutes](#). We expect study data to support the company's IND with the FDA in H2 CY24, which, if cleared, would enable Recce to start a multiple-dose global (including US sites) Phase II efficacy study in UTIs/urosepsis in Q4 CY24.

Phase III DFI study increases commercial potential

Following Recce's [recently announced](#) strategic partnership and memorandum of understanding (MoU) in South-East Asia with Indonesian biomedical company Etana, it plans to start a Phase III registrational study for topical R327 in diabetic foot infections (DFIs) in Indonesia in Q3 CY24. This marks the first major step towards a larger-scale clinical efficacy trial and potential commercialisation. While details are scarce, we assume the large majority of study costs will be covered by the Indonesian government and that positive results could lead to commercial launch in Indonesia and other [ASEAN](#) member state countries in H2 CY26.

Valuation: Raising rNPV to A\$661.3m

We continue to determine an rNPV for Recce applying a 12.5% discount rate to its four primary development programmes. After including the ASEAN market DFI R327 opportunity in our projections and rolling forward our model, we obtain a new rNPV valuation, inclusive of A\$3.0m Q324 estimated net debt as of 31 March 2024, of A\$661.3m (or A\$3.27 per share), versus A\$644.4m (or A\$3.16 per share) previously.

7 May 2024

Price **A\$0.66**
Market cap **A\$135m**

US\$0.65/A\$

Estimated net debt (A\$m) at 31 March 2024 3.0

Shares in issue 204.0m

Free float 56.4%

Code RCE

Primary exchange ASX

Secondary exchanges Frankfurt: R9Q, OTC: RECEF

Share price performance



%	1m	3m	12m
Abs	46.7	32.0	0.0
Rel (local)	48.0	29.6	(6.8)

52-week high/low	A\$0.75	A\$0.41
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Business description

Recce Pharmaceuticals is an Australian company developing its novel, broad-spectrum synthetic polymer anti-infective drugs for the treatment of several infectious diseases, including sepsis, burn wound infections, urinary tract infections/urosepsis and diabetic foot infections.

Next events

Start Phase II R327 (IV) study in urinary tract infections	H2 CY24
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Progress in the DFI and urosepsis/sepsis programmes

Recce has reported notable progress in its lead R327 anti-infective therapeutic programme in recent weeks. It is advancing the drug candidate as an IV formulation for the treatment of sepsis and for cUTIs and urosepsis, and in topical formulations for DFIs and burn wound infections. We believe that the sepsis/urosepsis and DFI programmes are the company's strongest opportunities and Recce highlighted progress on both fronts in its [recent business update](#).

IV R327 shows continued safety at higher dose intensities

We continue to view the IV formulation as Recce's strongest commercial opportunity, specifically the sepsis (and/or urosepsis) and cUTI indications. The company is prioritising development in this area as it continues to advance a Phase I/II study (trial ID ACTRN12623000448640 at anzctr.org.au) assessing the safety, tolerability and pharmacokinetics of IV R327 at faster infusion rates (compared to R327-001, [its initial single-dose IV R327 dose escalation trial](#)). Recce believes faster infusion rates could enable broader access to the drug in the primary care and acute patient care settings.

The company [reported in September 2023](#) that it had successfully completed a cohort of both males and females with a 3,000mg dose level at an infusion rate of 30 minutes, which the study's independent safety committee (ISC) unanimously deemed safe and well tolerated [in October](#). Recce has since completed dose cohorts in the study where the 3,000mg dose has been successfully infused (with favourable subsequent safety and tolerability results) at multiple infusion times, including one hour, 45 minutes, 20 minutes and 15 minutes.

Recce also took urine samples from the patients dosed with IV R327 throughout the study and found that R327 was present in these samples and, more notably, that these urine samples demonstrated anti-infective properties (as determined in their reported minimum inhibitory concentration drug activity), suggesting that the rapid infusion of R327 leads to urine concentrations capable of blocking bacterial growth in urine (which would be relevant to the UTI/urosepsis patient population). The company has identified 30 minutes as the potential optimum infusion time to reach the most potentially efficacious drug activity in the urinary tract.

Subsequently, the company is expanding the scope of the ongoing rapid infusion Phase I/II study to increase to a higher 4,000mg dose level. The study's ISC committee in April cleared the trial to include a cohort of six participants who will receive [4,000mg of R327 dosed over 30 minutes](#). Subject recruitment has commenced and Recce expects to complete dosing in the coming weeks.

Based on the data from the dose-escalation phase in healthy volunteers of the above trial, optimal dosing levels will be decided for the subsequent clinical studies for IV R327 in UTIs and/or urosepsis.

US IND filing expected in H2 CY24

We expect Recce to submit an IND application to the US FDA in H2 CY24 and then start a multiple-dose global (including US sites) Phase II efficacy study in UTIs/urosepsis in Q4 CY24. We assume this study will recruit c 40 to 80 patients with cUTIs and will be completed in H2 CY25. While this US-centric trial will technically be termed a Phase II study, we understand it will be designed to serve as one of the two studies necessary to meet a US New Drug Application (NDA). We assume that if the results of this urosepsis study are positive, a larger pivotal Phase III study would then begin and it could serve as the final study required for US registration. We anticipate that this Phase III study would be designed to assess both patients with cUTIs, as well as patients with sepsis (both urosepsis as well as other forms of sepsis).

We anticipate the start of this registration-enabling study (in Europe and the United States) in H2 CY25 or H1 CY26, and we believe it will be designed to support marketing approval applications for both sepsis and cUTIs. We maintain our estimate for potential approval and commercialisation in sepsis in H2 CY28, and as we now expect this pivotal Phase III trial to include cUTI patients, we are pushing forward our projected timeline for launch and approval in the cUTI indication to H2 CY28 as well (from CY29 previously).

Recce reaches GMP manufacturing milestone

Recce [recently announced](#) that it has successfully completed, under Good Manufacturing Practice (GMP) guidelines, a production batch validating its capability to make up to 5,000 GMP doses of R327 per week. For the production batch, the company temporarily transported its manufacturing equipment from its Macquarie Park (Australia) facility to a third-party cleanroom GMP facility, where it produced 5,000 R327 doses under GMP including the final manufacturing step (fill and finish). The company reports that this represents a first GMP-scale validation of the reproducible and versatile nature of the company's patented manufacturing processes. The ability to produce high dose quantities is key as the company prepares to start larger-scale studies, notably the topical R327 study for DFI in Indonesia described below. Further, GMP manufacturing capabilities and certifications are a key requirement for the company to proceed with an IND application filing with the US FDA, in order to commence clinical studies in the US. As described above, the company plans to start US studies in Q4 CY24.

Topical R327 DFI programme advancing to Indonesian Phase III

As discussed in [our prior note](#), Recce is advancing a topical formulation of R327 for DFIs and results to date from an ongoing Phase I/II study in skin and soft tissue DFIs first [announced in January 2024](#) (and discussed in further detail [in an earlier note](#)) have met all primary endpoints. The study's ISC at Liverpool Hospital NSW has reviewed all the data to date from the study (where R327 was dosed either daily or every other day) and confirmed the study is achieving its primary safety, tolerability and efficacy endpoints (including resolving or curing bacterial DFIs). The ISC unanimously agreed to expand the study to multiple additional sites in Australia (as well as outside the country) and to broaden the study's inclusion criteria to include broader stages of DFIs. Recce expects to include additional study sites in the coming months.

More notably, on the heels of Recce's [recently announced](#) strategic partnership and MoU in South-East Asia with Indonesian biomedical company Etana, the company has indicated that it is planning to start a Phase III registrational study for topical R327 in DFI in Indonesia in Q3 CY24. This would be a significant shift for the company, as it would mark the first major step towards a larger-scale clinical efficacy trial and towards potential commercialisation. While details are scarce, we believe that the Phase III study will be placebo controlled and likely recruit c 250 to 300 patients and could be completed before end-CY25. We also note that the Indonesian government was supportive of the MoU, citing the need for novel, effective anti-infective therapies to combat antimicrobial resistance. Given that there has been a mention of '[substantial government support](#)' for the initiative, we assume that the large majority of the Phase III Indonesian topical R327 clinical trial costs will be covered by the Indonesian government.

If results are positive, we believe they could be used to support regulatory approval applications for DFI in Indonesia and other Association of Southeast Asian Nations (ASEAN) member state countries (which collectively cover 670 million individuals). We note that more than 10% of Indonesia's population (or c 19.5 million people) have diabetes, resulting in an increased risk for DFIs. We now model that topical R327 could be launched in Indonesia and other ASEAN countries in H2 CY26, and that Recce will rely on a commercial distribution partner in this area and collect net royalties at 25% of net sales.

We assume that the Phase III Indonesian study will not be sufficient alone to support registration applications in the US or Europe, but we note that Recce is planning to file a US IND for the topical R327 formulation in Q4 CY24, which would permit the initiation of a US study of the topical formulation.

Diabetic foot ulcers are frequent complications of patients who have diabetes mellitus, if the condition is not adequately controlled. Approximately [37 million people](#) have diabetes in the United States. Of them, about [2–4%](#) will obtain foot ulceration each year, of which 50–60% will result in DFIs, the leading cause of foot morbidity in diabetic patients. Diabetes is reported to be the leading cause of non-traumatic lower extremity amputations in the US. Recce believes that topical R327 could potentially be useful in mild DFIs (as more advanced cases require systemic antibiotics), and the recently reported results (January 2024) on five patients provide signs of proof-of-concept and early indications of efficacy (in terms of clearing infection) for topical R327 in this indication.

We continue to estimate that the company could start a Phase III pivotal programme in the US (and Europe) for DFIs in CY25, which we model could lead to launch in these markets in CY29.

US\$2.2m US defence grant provides validation for R327G

In addition to assessing topical R327 in DFI, the company is also assessing the topical formulation as a treatment for burn wound infections and has been conducting a [Phase I/II trial for topical R327 in burn wound infections](#), sponsored by the West Australian health department and conducted at Fiona Stanley Hospital; the trial remains ongoing with stage 1 of the study having been completed. The company recently announced that the US Department of Defence (DoD) has recommended US\$2.2m of funding to Recce to further support the development of a topical gel formulation of R327 (R327G) as a treatment for burn wound infections. In our view, this provides notable external validation of the potential of this product to treat burn wounds and prevent complications such as bacteremia and sepsis. Recce expects to receive the grant funding in Q2 CY24 and we expect it to be used towards potential US clinical trials for burn wounds, which could start in CY25, in our view (following the clearance of the US IND application for the topical formulation).

Financials: Runway into Q4 CY24

In Recce's recent [quarterly cash flow \(4C statement\) update](#) (for the period ending 31 March), it reported a net operating cash burn rate of A\$4.7m, above our forecast of A\$3.5m, driven by A\$3.6m in gross R&D expenditures during the quarter. We believe the increase in R&D spending (vs the quarterly rate implied by the A\$4.8m reported for H124) is due to increased activity for the topical and IV R327 programmes, including the ongoing Phase I/II rapid infusion study as well as preclinical activities and preparations for the IND filings (for both topical and IV R327) in H2 CY24.

Recce [announced in March](#) that it is receiving A\$11.18m as an R&D advance credit through an arrangement with Endpoints Capital, whereby Endpoints provided the funding to Recce as an advance credit for the R&D tax credit rebates that Recce expects to receive for FY23, FY24 and FY25. In Q324 it reported that it had received A\$9.3m in net borrowings and we believe it should receive another c A\$1.9m in proceeds in the coming weeks. Altogether the company finished the quarter with A\$8.5m in cash and equivalents. We estimate that the company's gross debt at quarter-end (31 March) was A\$11.5m, up from A\$2.2m at H124, and we calculate the Q324e net debt at A\$3.0m (vs A\$1.8m net cash at H124).

Following the 4C statement, we have made very minor adjustments to our expenditure estimates, but now expect the company to receive c A\$3.4m from the R327G US DoD grant in the current quarter (Q424). Hence we have increased our FY24 revenue estimate (primarily consisting of grant income and R&D tax credits) to A\$9.2m, up from A\$5.8m, previously. We now assume an FY24 net operating cash burn rate of A\$13.7m, down from A\$16.9m previously. As a result, we now assume

that the company's cash on hand should fund operations into Q4 CY24 (Q225), versus Q3 CY24 previously. We continue to model that the company will raise A\$60m before the end of FY25.

We have kept our FY25 and medium-term operating cost assumptions essentially unchanged, and we continue to expect that the company will be entitled to R&D tax credit proceeds (or grants) from the Australian government at 43.5% of prior-year R&D expenditure levels. Our FY25 net operating cash burn estimate is A\$58.1m, little changed from our prior A\$58.2m estimate.

We continue to expect R&D expenditure to rise significantly in FY25, as we project costs for the US Phase II multi-dose UTI/urosepsis study will start to ramp up in late CY24, and we anticipate increasing costs for the DFI programme as the company files an IND for the topical formulation to engage with US clinical trial sites. However, as mentioned earlier, we assume that Recce's own costs for the Phase III DFI Indonesian study will be limited (as we anticipate that the Indonesian government will fund the majority of the study). Altogether, we assume clinical trial activities for each of the four sought indications in our model (sepsis, UTIs, DFIs and burn wounds) will ramp up in FY25. Any delays to the start of such activities would reduce our funding estimates over this period but may push back our potential launch forecasts.

Depending on the availability of capital, the company may decide to prioritise certain programmes, which may affect the timing of launches in non-prioritised indications and affect our overall valuation. Our current funding model assumes Recce will advance all four programmes in parallel. However, if it prioritises sepsis (and/or urosepsis) and cUTIs and puts its remaining development programmes on hold until the initial R327 commercial approval, this would reduce its overall funding need as it could subsequently apply post-launch commercial revenue towards resuming R&D and product development activities in the remaining targeted indications. In addition, partnerships and/or non-dilutive forms of funding (such as third-party sponsorship of clinical trials) could also reduce the future funding need, although these are not specifically included in our forecasts.

We view sepsis as the primary driver of the company's valuation and expect Recce will prioritise the sepsis (and/or urosepsis) and cUTI indications. Assuming the company continues to develop all four planned clinical-stage indications, we continue to assume Recce would need to raise an additional A\$200m in total net proceeds by FY29 before becoming sustainably cash flow positive. As per the usual Edison methodology, we model these raises as illustrative debt.

While we now project the company will begin to receive commercial revenue in FY27 (H2 CY26) from the sales (through a commercial partner) of IV R327 in Indonesia and other ASEAN territories, we do not believe such revenue will fully offset R&D costs for the ongoing US/global R327 trials at the time and hence we continue to forecast positive cash flows only in FY29.

We note that the company has an at-the-market (ATM) equity financing facility with Acuity Capital that expires in January 2026, which provides it with up to A\$20m of standby equity capital. Recce is not required to use the ATM and may terminate it at any time without cost or penalty.

Valuation

We continue to determine an rNPV for Recce, applying a 12.5% discount rate to its four primary development programmes. However, we previously had not included ASEAN countries for any of the company's development programmes, but given the company's upcoming Phase III Indonesian DFI study (starting in Q3 CY24) we now assume that the company will launch topical R327 for DFI in Indonesia and other ASEAN countries with a commercial distribution partner, starting in H2 CY26, and that Recce will be entitled to net royalties at 25% of net sales. We assume that the prevalence of diabetes in ASEAN countries is c 47m, with 3% obtaining diabetic foot ulcers in a given year, and of these, 55% will be infectious and c 25% of such infections can be treated with topical IV R327, leading to a potential addressable market of c 195,000 cases per year in the

region. At 20% assumed peak market share, this would translate into c A\$50m in peak sales, with Recce entitled to a 25% royalty according to our forecasts. We apply a 25% probability of success to the ASEAN market DFI opportunity and currently obtain a rNPV of A\$7m in our valuation for this opportunity.

After including the ASEAN DFI programme and rolling forward our model, we now obtain a new rNPV valuation, inclusive of A\$3.0m Q324e net debt, of A\$661.3m (or A\$3.27 per share), versus A\$644.4m (or A\$3.16 per share) previously.

As stated earlier, our model assumes all future financing needs will be raised through illustrative debt, as per usual Edison methodology. If our projected funding need of A\$200m is raised through equity issuances at the prevailing market price of c A\$0.66, our effective value per share would decrease to A\$1.70 (including cash raised via equity).

Exhibit 1: Recce Pharmaceuticals rNPV valuation

Product	Indication	Launch	Sales (A\$m) in 2032	NPV (A\$m)	Probability of success	rNPV (A\$m)	rNPV/basic share (A\$)
R327 (IV)	Sepsis	H2 CY28	3,599	4,297	15%	629	3.09
R327 (IV)	Complicated UTI	H2 CY28	420	496	15%	61	0.30
R327 (topical)	Burn wounds	CY28	275	277	20%	43	0.21
R327 (topical)	Diabetic foot infections (ex-ASEAN)	CY29	128	129	15%	8	0.04
R327 (topical)	Diabetic foot infections (ASEAN)	H2 CY26	53	27	25%	7	0.03
Corporate costs				(77.9)		(77.9)	(0.38)
Estimated net cash/(debt) at 31 March 2024				(3.0)		(3.0)	(0.01)
Total equity value						661.3	3.27

Source: Edison Investment Research

Exhibit 2: Financial summary

	A\$'000s	2020	2021	2022	2023	2024e	2025e
Year end 30 June		IFRS	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS							
Revenue		1,122	1,857	3,085	4,311	9,156	6,692
Cost of Sales		0	0	0	(0)	(0)	(0)
Gross Profit		1,122	1,857	3,085	4,311	9,156	6,692
Sales, General & Administrative		(3,136)	(9,511)	(7,677)	(9,779)	(7,591)	(8,078)
Net Research & Development		(2,071)	(5,657)	(6,285)	(7,330)	(15,385)	(51,154)
EBITDA		(4,085)	(13,311)	(10,878)	(12,797)	(13,820)	(52,540)
Depreciation & amortisation of intangible assets		0	0	0	0	0	0
Depreciation, amortisation & other		(201)	(296)	(188)	(217)	(380)	(328)
Normalised Operating Profit (ex. amort, SBC, except.)		(4,231)	(8,389)	(10,809)	(12,689)	(14,200)	(52,868)
Operating profit before exceptionals		(4,286)	(13,607)	(11,065)	(13,014)	(14,200)	(52,868)
Exceptionals including asset impairment		0	0	0	54	0	0
Other		0	0	0	0	0	0
Reported Operating Profit		(4,286)	(13,607)	(11,065)	(12,960)	(14,200)	(52,868)
Net Finance income (costs)		(31)	94	79	(117)	(437)	(5,444)
Profit Before Tax (norm)		(4,317)	(13,513)	(10,986)	(13,131)	(14,637)	(58,312)
Profit Before Tax (FRS 3)		(4,317)	(13,513)	(10,986)	(13,077)	(14,637)	(58,312)
Tax		0	0	0	0	0	0
Profit After Tax and minority interests (norm)		(4,317)	(13,513)	(10,986)	(13,131)	(14,637)	(58,312)
Profit After Tax and minority interests (FRS 3)		(4,317)	(13,513)	(10,986)	(13,077)	(14,637)	(58,312)
Average Basic Number of Shares Outstanding (m)		127.2	155.4	174.1	174.0	191.1	204.0
EPS - normalised (A\$)		(0.03)	(0.09)	(0.06)	(0.08)	(0.08)	(0.29)
EPS - normalised and fully diluted (A\$)		(0.03)	(0.09)	(0.06)	(0.08)	(0.08)	(0.29)
EPS - (IFRS) (A\$)		(0.03)	(0.09)	(0.06)	(0.08)	(0.08)	(0.29)
Dividend per share (A\$)		0.0	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET							
Fixed Assets		505	501	439	608	537	341
Intangible Assets		0	0	0	0	82	82
Tangible Assets		505	501	439	608	455	259
Investments in long-term financial assets		0	0	0	0	0	0
Current Assets		2,739	21,181	12,185	1,947	5,475	7,360
Short-term investments		0	0	0	0	0	0
Cash		2,682	20,873	11,582	1,562	4,639	6,524
Other		57	308	603	386	836	836
Current Liabilities		(885)	(1,078)	(2,447)	(4,850)	(4,648)	(4,648)
Creditors		(885)	(1,078)	(2,447)	(1,802)	(2,414)	(2,414)
Short term borrowings		0	0	0	(3,048)	(2,234)	(2,234)
Long Term Liabilities		(46)	(100)	(115)	(295)	(8,005)	(68,005)
Long term borrowings		0	0	0	0	(7,714)	(67,714)
Other long term liabilities		(46)	(100)	(115)	(295)	(291)	(291)
Net Assets		2,313	20,504	10,061	(2,589)	(6,641)	(64,953)
CASH FLOW STATEMENT							
Operating Income		(4,286)	(13,607)	(11,065)	(12,960)	(14,200)	(52,868)
Movements in working capital		253	144	1,532	(152)	751	0
Net interest and financing income (expense)		(31)	94	79	(117)	(437)	(5,444)
Depreciation & other		201	296	188	217	380	328
Taxes and other adjustments		55	5,218	256	325	0	0
Net Cash Flows from Operations		(3,807)	(7,856)	(9,010)	(12,687)	(13,506)	(57,984)
Capex and capitalised expenditures		(6)	(76)	(40)	(39)	(119)	(131)
Acquisitions/disposals		0	0	0	0	(116)	0
Interest received & other investing activities		0	0	0	0	0	0
Net Cash flows from Investing activities		(6)	(76)	(40)	(39)	(235)	(131)
Net proceeds from share issuances		6,980	26,338	287	102	10,585	0
Net movements in long-term debt		0	0	0	0	6,234	60,000
Dividends		0	0	0	0	0	0
Other financing activities		(888)	(215)	(528)	2,604	0	0
Net Cash flows from financing activities		6,092	26,123	(240)	2,706	16,819	60,000
Effects of FX on Cash & equivalents		0	0	0	0	0	0
Net Increase (Decrease) in Cash & equivalents		2,279	18,191	(9,291)	(10,020)	3,077	1,885
Cash & equivalents at beginning of period		403	2,682	20,873	11,582	1,562	4,639
Cash & equivalents at end of period		2,682	20,873	11,582	1,562	4,639	6,524
Closing net debt/(cash)		(2,682)	(20,873)	(11,582)	1,487	5,309	18,729
Lease debt		83	127	75	251	199	199
Closing net debt/(cash) inclusive of IFRS 16 lease debt		(2,599)	(20,746)	(11,507)	1,737	5,507	18,928
Free cash flow		(3,813)	(7,932)	(9,051)	(12,726)	(13,741)	(58,115)

Source: Company accounts, Edison Investment Research

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