EDISON

Recce Pharmaceuticals

Development update

Supportive advancements on the pipeline

Healthcare

Recce Pharmaceuticals has announced several positive developments in recent weeks relating to its therapeutic programmes, particularly for lead anti-infective candidate RECCE® 327 (R327). It entered a strategic collaboration with an Indonesian biomedical company, PT Etana Biotechnologies (Etana), which may support the engagement of relatively lower-cost clinical trial sites with potentially deep patient pools in South-East Asia (SEA). The company also recently disclosed positive efficacy results among five patients treated in its Phase I/II study of topical R327 in patients with diabetic foot infections (DFI), and it now plans to expand this programme to additional domestic and global sites. We have raised our valuation to reflect the rolling forward of our estimates and reductions in our R&D and SG&A cost projections, following the most recent quarterly cash flow update. We now obtain a risk-adjusted net present value (rNPV) of A$652.6m (or A$3.20/share), versus A$551.1m 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	3.2	(24.8)	(0.13)	0.0	N/A	N/A
06/25e	8.7	(55.3)	(0.27)	0.0	N/A	N/A

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

SEA MoU to support future trials

Recce recently announced that it has established a strategic partnership and memorandum of understanding (MoU) in SEA with Etana, which is designed to facilitate the assessment of Recce's antimicrobial compounds in late-stage clinical trials in Indonesia and potentially other SEA countries. The collaboration could be fruitful once Recce expands to later-stage global clinical trials, where having access to study sites in lower-cost jurisdictions will be crucial in managing R&D costs.

Phase I/II rapid infusion IV R327 study advancing

Recce's priority is to advance the intravenous (IV) formulation of R327, particularly for lead indication sepsis (and/or urosepsis) as well as complicated urinary tract infections (UTIs). The ongoing Phase I/II IV R327 study started assessing a 15-minute infusion rate in November, and we expect Recce to provide an update shortly. This trial is expected to inform optimal dosing levels and infusion rates for a subsequent Phase II study in UTI patients, which we project will start in H1 CY24.

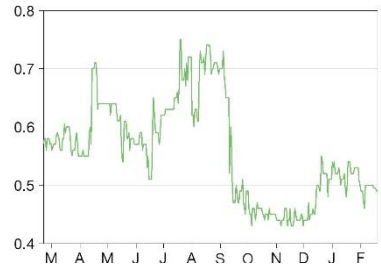
Valuation: Raising rNPV to A$652.6m

Given A$4.0m gross cash at Q4 CY23, we expect the company's funds on hand will maintain operations into Q2 CY24. With the recent 4C statement showing lower than expected cash burn rates, we have reduced our R&D and SG&A cost estimates and we now model that the company will raise A$15m in total funding (down from A$25m previously) before the end of FY24. After rolling our model forward and reflecting reduced cost estimates, we obtain an rNPV valuation of A$652.6m (or A$3.20 per share), up from A$551.1m (or A$2.71 per share) previously.

20 February 2024

Price	**A$0.48**
Market cap	**A$98m**
	US$0.65/A$
Estimated net cash (A$m) at 31 December 2023	2.4
Shares in issue	203.7m
Free float	56.4%
Code	RCE
Primary exchange	ASX
Secondary exchanges	Frankfurt: R9Q, OTC: RECEF

Share price performance



%	1m	3m	12m
Abs	(5.77)	13.95	(15.52)
Rel (local)	(8.88)	4.56	(19.37)
52-week high/low		A$0.8	A$0.4

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	H1 CY24
H124 financial results	February 2024

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Edison profile page

Collaboration in SEA to support R&D

Recce recently announced that it has established a strategic partnership and MoU in SEA with Indonesian biomedical company Etana. The MoU is designed to facilitate the development, assessment and potential commercialisation of Recce's broad-spectrum antimicrobial compounds in Indonesia (and in other jurisdictions, as agreed by the parties). Both the Australian and Indonesian governments, as well as Indonesia's National Research and Innovation Agency, support the collaboration as they seek to improve access to novel infectious diseases drugs to help combat antimicrobial resistance. More than 10% of Indonesia's population (or c 19.5 million people) have diabetes, which increases the risk of infections including UTIs, one of the indications under active development for the intravenous formulation of Recce's lead candidate R327, and DFIs, one of the focus development areas for topical R327.

Specific details around the collaboration, including whether any parties or agencies will contribute funding to support future trials involving Recce product candidates (in the regions covered by the collaboration), have not been disclosed. The company is in discussions with Indonesian parties to assess research and clinical projects and it expects to enter into formal agreements in H1 CY24. The Indonesian government has provided access to hospitals for clinical trials, as well as preclinical research facilities. We assume that Etana, which was founded in 2014 and has its own drug development capabilities targeting SEA markets, will at minimum help Recce to recruit clinical trial sites and study investigators in Indonesia, and potentially also other ASEAN member state countries (which collectively cover 670 million individuals). Hence, we see the potential for the collaboration to be particularly helpful to Recce once it expands to later-stage (eg Phase III or pivotal stage) global clinical trial development, where having access to study sites in lower-cost jurisdictions (such as Indonesia and some of the ASEAN countries) will be crucial in managing R&D costs.

We remind readers that in late CY23 Recce secured a landmark commitment from the Australian government to provide up to A$55m in future cash rebates to reimburse upcoming R&D expenditure directed towards the company's proprietary synthetic anti-infective programmes to June 2025. Notably, this binding agreement with the Australian government's Department of Industry, Science and Resources (AusIndustry) extends the rebate programme that customarily reimburses 43.5% of eligible R&D expenditures incurred within Australia, to cover the anti-infective R&D activities Recce undertakes anywhere in the world. We expect that the bulk of Recce's upcoming R&D funding will be directed towards its lead synthetic anti-infective candidate, R327, which is designed to work on multiple levels by interrupting bacterial energy production and cell division and affecting cell membrane permeability, to continuously kill bacteria. In preclinical studies R327 has been shown to be effective against a broad spectrum of Gram-positive and Gram-negative bacteria, including all ESKAPE pathogen bacterial strains (superbugs). The company is advancing the drug candidate as an IV formulation for the treatment of sepsis and for complicated UTIs (cUTIs) and urosepsis, and in topical formulations for burn wound infections and DFIs.

Topical R327 advancing in DFIs after positive efficacy data

Recce announced in January 2024 that its Phase I/II study assessing topical R327 in DFIs met all primary endpoints and it is working to expand the study both domestically and internationally. In October 2022, Recce first announced that it would be assessing its topical (spray-on) R327 formulation to assess mild DFIs, and in December 2022, it received Australian approval to start an open-label Phase I/II study at the South West Sydney Limb Preservation and Wound Research Unit. The study was initially designed to assess topical R327 in this indication in up to 32 patients with mild skin and soft tissue DFIs.

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, and among 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 on five patients provide signs of proof-of-concept for topical R327 in this indication.

In the trial, patients with mild skin and soft tissue DFIs were treated with topical R327 either daily or every second day, for 14 days. The company reports that the trial met its primary endpoints of resolving or curing DFIs, and the company is now looking to expand clinical trial sites both in Australia and internationally.

Exhibit 1: Summary of treated patients in the Australian diabetic foot infection Phase I/II study

Patient	Application frequency	Age (yrs)/ Gender	Wound location (aspect)	Clinical response
1	Daily	32/M	Left forefoot lateral	Escalated to systemic therapy
2	Every other day	55/M	Right hallux plantar	Infection resolved/cured
3	Every other day	51/M	Left forefoot plantar	Infection resolved/cured
4	Daily	70/M	Left forefoot plantar	Infection resolved/cured
5	Daily	64/M	Right hallux dorsal	Infection resolved/cured

Source: Recce Pharmaceuticals

Of the five treated patients, four of them had their infection cleared and resolved fully with topical R327 therapy. The only exception was Patient 1, who was already on systemic therapy prior to commencing R327. This patient had several comorbidities (including obesity and neuropathic infection) and his treatment was escalated to systemic therapy at Day 15 (ie after 14 days of R327 treatment). It was noted that at this point, the initial redness and swelling of the wound, as well as its overall size, had already reduced versus baseline. However, investigators still escalated the patient to systemic therapy given the complexities of the significant wound and comorbidities. At the 28-day follow-up (around two weeks after escalation to systemic therapy), the infection was resolved and all therapy was ceased.

For all the remaining cases, R327 led to complete cure at the end of the 14-day therapy period, and in all cases, at the midpoint of therapy (Day 7), a significant reduction of the infection was already noted with associated rapid improvement.

While we recognise that thus far the data set reflects only a limited number of patients (five) treated with topical R327 in DFI, the early results are encouraging and we look forward to further updates as the company expands its DFI programme to other study sites. At this point we maintain our existing probability of success assumption and market launch timing forecasts for R327 in DFI.

Current literature suggests that while topical application of antimicrobials may have merit in many cases (such as patients who do not tolerate oral antibiotics), there is limited high-quality evidence on the appropriate indications, dosages and pharmacokinetics and, consequently, treatment guidelines do not encourage the use of any currently approved topical anti-infective for treating mild DFIs. Hence, there is a considerable opportunity should topical R327 in a controlled setting demonstrate clinical benefit (such as the prevention of DFI progression or recurrence), although we remain cognisant of the historical challenges of topical drugs in this indication.

If the company's Phase II DFI trial expansion (to sites outside Australia) shows continued positive data for R327, we continue to estimate that the company could start a Phase III pivotal programme for DFIs in CY25, which we model could lead to launch in CY29.

We note that in addition to assessing topical R327 in DFI, 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, remains ongoing. In August 2023 the company announced that it had completed stage one of this investigator-led study and will proceed with stage two of the trial, which aims to access a greater population and compare the topical R327 treatment in a head-to-head manner against standard-of-care. Further updates are anticipated during CY24.

R327 continues to advance in rapid infusion trial

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 its continues to advance a Phase I/II study (trial ID ACTRN12623000448640 at anzctr.org.au) assessing the safety, tolerability and pharmacokinetics of R327 IV at faster infusion rates (compared to R327-001, its initial single-dose IV R327 dose escalation trial). The company expects that faster infusion rates could enable broader access to the drug in 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 at 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. The ISC then permitted the trial to proceed to the next planned dosing cohort of 3,000mg at a 15-minute infusion rate. In November, Recce reported that the first male and female subjects of this cohort had completed dosing (of 3,000mg) at this faster 15-minute infusion rate as part of the trial. To our knowledge, safety results are favourable to date and this cohort has been fully recruited. The ISC is expected to review urine and plasma drug concentration data shortly and we expect Recce to provide an update thereafter.

Based on the data from the dose escalation phase in healthy volunteers of the above trial, optimal dosing levels and infusion rates will be decided for the subsequent Phase II clinical study, which will be conducted in patients with uncomplicated or recurrent UTIs. We expect this Phase II trial to commence in the coming weeks (in H1 CY24) with likely readouts (including ex-vivo analysis) in Q2 or Q3 CY24. We expect insights from both trials to influence the design of the planned separate global (ie including US sites) Phase II multiple-dose efficacy trial in UTIs/urosepsis.

We expect Recce to submit an Investigational New Drug application to the US FDA and then start this separate multiple-dose Phase II efficacy study in UTIs/urosepsis in or around mid-CY24. We assume that if the results of the urosepsis study are positive, the pivotal Phase III programme (and overall commercial sepsis programme) would include all forms of sepsis. We anticipate the start of such pivotal sepsis studies (in Europe and the United States) in H2 CY25 and we maintain our estimate for potential approval and commercialisation in sepsis in H2 CY28.

Financials: Raise extends runway into CY24

Recce's latest 4C quarterly cash flow statement (for the quarter ending 31 December 2023, or fiscal Q224) showed a quarterly operating cash flow loss of A$2.29m, dampened by the receipt of a A$2.28m R&D tax rebate during the period. The company used the proceeds from the tax credit to pay down advances from Radium Capital (short-term borrowings specifically drawn as advance payments for the company's anticipated R&D tax credit proceeds, as described in our prior update note). Altogether the company ended the period with a gross cash balance of A$4.0m, and we continue to expect that going forward, the company will receive R&D tax credit proceeds (or grants) at 43.5% of prior-year R&D expenditure levels. During the quarter, the company reported A$3.6m in gross R&D costs and A$1.0m in SG&A-related cash expenses, itself down from A$1.5m from the three months ending 30 September 2023. For the half-year, gross R&D expenditures were A$6.5m, coming below our A$7.8m forecast.

Following the prior 4C quarterly update (for the period ending 30 September), as discussed in our prior update note, we estimated Q124 gross debt at A$3.85m. With the A$2.28m debt repayment in Q224, we estimate Q224 gross debt at A$1.57m and Q224 net cash at A$2.44m.

While H124 financial results are not expected until late February, given the H124 trends from the 4C statement, we have reduced our FY24 R&D and SG&A expense forecasts accordingly. We now expect FY24 R&D and SG&A expenses to be A$20.0m and A$7.6m respectively, down from A$25.0m, and A$10.0m respectively. We have also reduced our FY25 R&D and SG&A forecasts to A$51.2m and A$8.1m respectively, down from A$55.7m and A$10.4m respectively.

We continue to expect R&D expenditure to rise significantly in FY25 (starting H2 CY24), as we project costs for the US Phase II multi-dose UTI/urosepsis study will then start to ramp up, and as cited earlier, we anticipate increasing costs for the DFI programme with global trial site engagement.

We expect R&D spending to increase year-on-year in FY25 given the ramping up of clinical trial activities for each of the four sought indications in our model (sepsis, UTIs, DFIs and burn wounds). Any delays to the start of such activities would reduce our funding estimates over this period but may push back our potential launch forecasts.

We now anticipate FY24e and FY25e net operating cash burn rates of A$24.7m (down from A$32.7m previously) and A$54.9m (A$61.0m previously). We estimate the company's cash runway lasts into Q2 CY24 and model the company will raise A$15m (A$25m previously) in total additional funding (modelled as illustrative debt) before the end of FY24.

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 the company in the future 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 now assume Recce would need to raise an additional A$205m (vs A$225m previously) in total by FY29 before becoming sustainably cash flow positive. As per our usual Edison methodology, we model these raises as illustrative debt.

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. Aside from reductions to R&D and SG&A expenditures as described above, our core valuation and modelling assumptions are essentially unchanged (see our initiation note for details). After rolling forward our estimates and updating our forex assumptions (primarily assuming A$0.65/US$, versus A$0.66/US$ previously) we obtain a new rNPV valuation, inclusive of A$2.4m estimated Q224e net cash as of 31 December 2023, of A$652.6m (or A$3.20 per share), versus A$551.1m (or A$2.71 per share) previously. The increase in rNPV is largely driven by the

reduction in near-term cost estimates as well as the present-value effects of rolling forward our forecasts.

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$205m is raised through equity issuances at the prevailing market price of c A$0.48, our effective value per share would decrease to A$1.36 (including cash raised via equity).

Exhibit 2: 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	4,185	15%	624	3.06
R327 (IV)	Complicated UTI	CY29	387	446	15%	53	0.26
R327 (topical)	Burn wounds	CY28	275	268	20%	41	0.20
R327 (topical)	Diabetic foot infections	CY29	128	125	15%	7	0.03
Corporate costs				(75.6)		(75.6)	(0.37)
Estimated net cash at 31 December 2023				2.4		2.4	0.01
Total equity value						652.6	3.20

Source: Edison Investment Research

Exhibit 3: Financial summary

A$(000)	2020	2021	2022	2023	2024e	2025e
Year end 30 June	IFRS	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS						
Revenue	1,122	1,857	3,085	4,311	3,188	8,700
Cost of Sales	0	0	0	(0)	(0)	(0)
Gross Profit	1,122	1,857	3,085	4,311	3,188	8,700
Sales, General & Administrative	(3,136)	(9,511)	(7,677)	(9,779)	(7,591)	(8,078)
Net Research & Development	(2,071)	(5,657)	(6,285)	(7,330)	(20,000)	(51,154)
EBITDA	(4,085)	(13,311)	(10,878)	(12,797)	(24,403)	(50,532)
Depreciation & amortisation of intangible assets	0	0	0	0	0	0
Depreciation, amortisation & other	(201)	(296)	(188)	(217)	(157)	(374)
Normalised Operating Profit (ex. amort, SBC, except.)	(4,231)	(8,389)	(10,809)	(12,689)	(24,560)	(50,906)
Operating profit before exceptionals	(4,286)	(13,607)	(11,065)	(13,014)	(24,560)	(50,906)
Exceptionals including asset impairment	0	0	0	54	0	0
Other	0	0	0	0	0	0
Reported Operating Profit	(4,286)	(13,607)	(11,065)	(12,960)	(24,560)	(50,906)
Net Finance income (costs)	(31)	94	79	(117)	(249)	(4,368)
Profit Before Tax (norm)	(4,317)	(13,513)	(10,986)	(13,131)	(24,809)	(55,274)
Profit Before Tax (FRS 3)	(4,317)	(13,513)	(10,986)	(13,077)	(24,809)	(55,274)
Tax	0	0	0	0	0	0
Profit After Tax and minority interests (norm)	(4,317)	(13,513)	(10,986)	(13,131)	(24,809)	(55,274)
Profit After Tax and minority interests (FRS 3)	(4,317)	(13,513)	(10,986)	(13,077)	(24,809)	(55,274)
Average Basic Number of Shares Outstanding (m)	127.2	155.4	174.1	174.0	191.0	203.7
EPS - normalised (A$)	(0.03)	(0.09)	(0.06)	(0.08)	(0.13)	(0.27)
EPS - normalised and fully diluted (A$)	(0.03)	(0.09)	(0.06)	(0.08)	(0.13)	(0.27)
EPS - (IFRS) (A$)	(0.03)	(0.09)	(0.06)	(0.08)	(0.13)	(0.27)
Dividend per share (A$)	0.0	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET						
Fixed Assets	505	501	439	608	613	417
Intangible Assets	0	0	0	0	0	0
Tangible Assets	505	501	439	608	613	417
Investments in long-term financial assets	0	0	0	0	0	0
Current Assets	2,739	21,181	12,185	1,947	1,238	1,160
Short-term investments	0	0	0	0	0	0
Cash	2,682	20,873	11,582	1,562	852	774
Other	57	308	603	386	386	386
Current Liabilities	(885)	(1,078)	(2,447)	(4,850)	(4,850)	(4,850)
Creditors	(885)	(1,078)	(2,447)	(1,802)	(1,802)	(1,802)
Short term borrowings	0	0	0	(3,048)	(3,048)	(3,048)
Long Term Liabilities	(46)	(100)	(115)	(295)	(13,815)	(68,815)
Long term borrowings	0	0	0	0	(13,520)	(68,520)
Other long-term liabilities	(46)	(100)	(115)	(295)	(295)	(295)
Net Assets	2,313	20,504	10,061	(2,589)	(16,813)	(72,087)
CASH FLOW STATEMENT						
Operating Income	(4,286)	(13,607)	(11,065)	(12,960)	(24,560)	(50,906)
Movements in working capital	253	144	1,532	(152)	0	0
Net interest and financing income (expense)	(31)	94	79	(117)	(249)	(4,368)
Depreciation & other	201	296	188	217	157	374
Taxes and other adjustments	55	5,218	256	325	0	0
Net Cash Flows from Operations	(3,807)	(7,856)	(9,010)	(12,687)	(24,652)	(54,900)
Capex and capitalised expenditures	(6)	(76)	(40)	(39)	(161)	(178)
Acquisitions/disposals	0	0	0	0	0	0
Interest received & other investing activities	0	0	0	0	0	0
Net Cash flows from Investing activities	(6)	(76)	(40)	(39)	(161)	(178)
Net proceeds from share issuances	6,980	26,338	287	102	10,585	0
Net movements in long-term debt	0	0	0	0	13,520	55,000
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	24,105	55,000
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)	(709)	(78)
Cash & equivalents at beginning of period	403	2,682	20,873	11,582	1,562	852
Cash & equivalents at end of period	2,682	20,873	11,582	1,562	852	774
Closing net debt/(cash)	(2,682)	(20,873)	(11,582)	1,487	15,716	28,740
Lease debt	83	127	75	251	251	251
Closing net debt/(cash) inclusive of IFRS 16 lease debt	(2,599)	(20,746)	(11,507)	1,737	15,966	28,990
Free cash flow	(3,813)	(7,932)	(9,051)	(12,726)	(24,814)	(55,078)

Source: Company accounts, Edison Investment Research

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