EDISON

Recce Pharmaceuticals

Pipeline and funding update

R327 continues to progress in clinical trials

Healthcare

Recce Pharmaceuticals raised A$11.0m (gross) in September and October. Most of the proceeds (A$6m) will be directed towards the company's clinical programmes for lead anti-infective candidate RECCE® 327 (R327), including the ongoing Phase I/II study of the IV formulation in healthy volunteers and in patients with uncomplicated or recurrent urinary tract infections (UTIs). This study continues to advance, with the company recently dosing healthy subjects with the 3,000mg dose over a 15-minute infusion period, following a favourable safety review of this dose over a 30-minute infusion. We model that Recce is currently funded into CY24 and expect the company to seek additional funding, which may come from partnerships or non-dilutive arrangements. Following minor adjustments to our forecasts, we now obtain an rNPV valuation of A$551.1m (or A$2.71 per share), versus A$562.4m 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	3.2	(32.9)	(0.17)	0.0	N/A	N/A
06/25e	10.9	(61.3)	(0.30)	0.0	N/A	N/A

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

Phase I/II rapid infusion IV R327 study advancing

Recce's priority is to advance the IV formulation of R327, particularly for lead indication sepsis (and/or urosepsis) as well as complicated UTIs. The company is conducting a Phase I/II study assessing R327 IV at faster infusion rates (than its earlier R327-001 trial). The study's independent safety committee (ISC) in October unanimously agreed that R327 is safe and well tolerated at a 30-minute infusion rate of 3,000mg. The ISC permitted the trial to proceed to the next planned dosing cohort of 3,000mg at a 15-minute infusion rate, and in November, Recce reported that the first subjects of this cohort had successfully completed dosing this faster 15-minute infusion rate. The Phase I/II clinical trial is expected to inform optimal dosing levels and infusion rates for a subsequent Phase II study, to be conducted in patients with uncomplicated or recurrent UTIs. We expect this Phase II trial to commence shortly with likely readouts (including ex-vivo analysis) in Q2 CY24. We expect insights from both trials to influence the design of the planned Phase II multiple-dose efficacy trial in UTIs/urosepsis (c 25% of all sepsis cases are caused by UTIs), which we expect to start in mid-CY24.

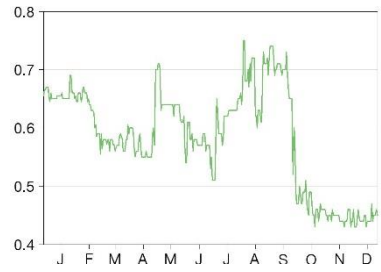
Valuation: Financing adjusts rNPV to A$551.1m

We now model that the company will raise A$25m in total funding (down from A$37.5m previously) before the end of FY24. We continue to assume a potential H2 CY28 R327 launch in urosepsis. After rolling our model forwards and adjusting forex estimates, we obtain a new rNPV valuation, inclusive of A$4.8m estimated pro-forma net cash as of 30 September 2023, of A$551.1m (or A$2.71 per share), down from A$562.4m (or A$3.15 per share) previously, with the minor decrease largely due to the relative strengthening of the Australian dollar versus the US dollar. Our per share valuation is also reduced due to the increased number of shares outstanding following the recent (H2 CY23) financings.

13 December 2023

Price	**A$0.44**
Market cap	**A$90m**
	US$0.66/A$
Pro forma estimated net cash (A$m) at 30 September 2023	4.8
Shares in issue (post A$11m financing in H2 CY23 and including shortfall shares issued in October)	203.7m
Free float	56.4%
Code	RCE
Primary exchange	ASX
Secondary exchanges	Frankfurt: R9Q, OTC: RECEF

Share price performance



%	1m	3m	12m
Abs	(2.2)	(25.0)	(31.3)
Rel (local)	(5.7)	(25.4)	(32.0)
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 (Phase II-ready), burn wound infections (Phase I/II) and urinary tract infections/urosepsis.

Next events

Start Phase II R327 (IV) study in urinary tract infections	Q4 CY23/Q1 CY24
Interim results from topical R327 studies in DFI	Q4 CY23

Analyst

Pooya Hemami OD MBA CFA +1 646 653 7026

healthcare@edisongroup.com

Edison profile page

Capital raise of A$11m extends cash runway

Recce in September 2023 completed a two-stage equity financing consisting of a private placement of A$8m (gross, for 18.18m shares) to institutional and professional investors and an entitlement offer to existing investors (offering one new share for every 26 existing shares held), which closed on 27 September and raised A$2.7m (gross, for 6.17m shares). In October, the company announced it had received additional commitments totalling c A$0.3m (for 0.698m shares) to compensate for the shortfall under the entitlement offer, which has since closed. The total gross proceeds for all these financings is A$11m. All these issuances were priced at A$0.44/share, or a 36.6% discount to the 15-day volume weighted average price (VWAP) prior to the announcement of the placement on 11 September. We note that as part of these transactions, Fidelity International (FIL) has become a substantial holder of Recce shares, owning 15.14m shares as of 18 September (c 7.4% of current shares outstanding).

The company has specified that it plans to use A$6m of the funding for clinical trials for lead candidate R327. This includes the ongoing Phase I/II study (trial ID ACTRN12623000448640 at anzctr.org.au) of the IV formulation of the drug, as well as the two Phase II studies of the topical formulations (one in burn wound infections and one for diabetic foot infections, or DFIs). It also intends to apply A$2m to advance its preclinical portfolio of anti-infective candidates (including in vitro, in vivo and ex vivo studies), A$1m to strengthen its manufacturing capabilities (including a US geographical expansion) and A$2m for general working capital purposes. Overall, the capital raise removed a near-term funding risk, and we see the participation of institutional investors in the placement as positive, indicating support and confidence in the commercial potential of Recce's pipeline and in candidate R327, in particular.

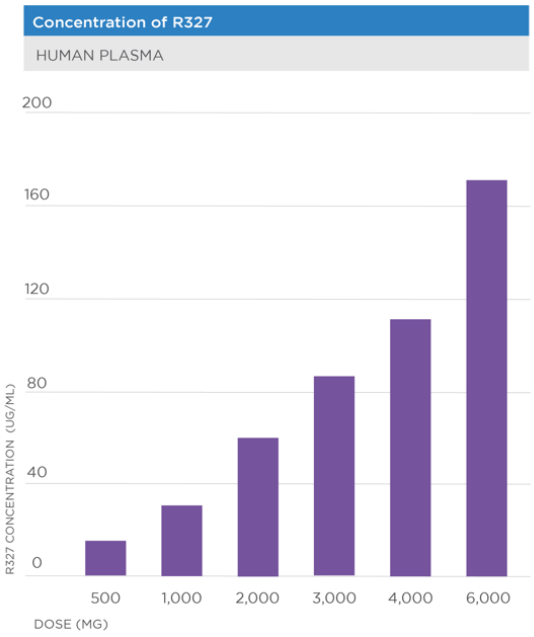
R327 shows encouraging anti-infective profile

As explained in our initiation note, Recce's lead candidate, R327, is a synthetic anti-infective candidate that works on multiple levels by interrupting bacterial energy production, cell division and affecting cell membrane permeability, to continuously kill bacteria. In preclinical studies R327 has 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 diabetic foot infections.

Initial single dose IV R327 study showed favourable safety and drug kinetics

In July 2023 Recce reported the completion of its data review for the previous single dose-escalation Phase I trial (Study R327-001) that tested R327 at a slower IV infusion rate (with the drug dosed over a 60-minute period) and at doses up to 6,000mg. The study was an ascending-dose, randomised, placebo-controlled first-in-human study assessing the safety and pharmacokinetics (PK) of a single dose of R327 in healthy male subjects, with 60 receiving R327 and 20 receiving placebo. All enrolled subjects completed dosing and the trial without interruption. The drug was found to be safe and well-tolerated and there were no serious adverse events and no clinically significant changes were noted in any haematology, chemistry, urinalysis, cardiac or vital sign parameters. In terms of PK, the study showed a consistent, linear and proportional increase in plasma drug concentration across the measured doses of R327 (from 500mg to 6,000mg).

Exhibit 1: Dose-dependent increases in plasma R327 concentration



R327 dosed subjects (60 total)

R327 dose (mg)	Concentration of R327 in Human Plasma - CMAX Plasma (ug/ml)
500	15.792
1,000	31.584
2,000	60.63
3,000	86.01
4,000	111.86
6,000	171.55

Source: Recce Pharmaceuticals press release 20 July 2023

R327 was found to concentrate in the urine, also in a dose-dependent manner, at concentrations up to 21-fold higher than in the plasma. This result makes the drug particularly promising for UTIs and urosepsis, given that 25–30% of sepsis cases are believed to originate in the urinary tract.

Exhibit 2: Increased and dose-dependent concentrations of R327 in urine

R327 dose (mg)	CMAX Plasma (ug/ml)	CMAX Urine (ug/ml)	Ratio - urine/plasma
500	**15.792**	**251.45**	**16x**
1,000	**31.584**	**520.76**	**17x**
2,000	**60.63**	**827.67**	**14x**
3,000	**86.01**	**738.84**	**9x**
4,000	**111.86**	**2304.88**	**21x**
6,000	**171.55**	**2682.76**	**16x**

Source: Recce Pharmaceuticals press release 20 July 2023

The company also cited an independent study showing that R327 in the presence of human urine could reduce the number of visible *E. coli* bacteria by over 99.99% in a matter of minutes.

R327 continues to advance in rapid infusion trial

As explained previously, Recce is now conducting a Phase I/II study (trial ID ACTRN12623000448640 at anzctr.org.au) assessing the safety, tolerability and PK of R327 IV at faster infusion rates. The company expects that faster infusion rates could enable broader access to the drug in primary care and acute patient care settings.

After announcing in August that R327 was safe and well-tolerated at this 2,500mg dose level when administered at two faster infusion rates (the durations of the tested infusion rates are not yet specified) in both males and females, the company reported in September that it had successfully completed a cohort of both of males and females at a 3,000mg dose level at an infusion rate of 30 minutes. The study's ISC in October unanimously agreed that R327 is safe and well tolerated at a

30-minute infusion rate of 3,000mg in both males and females, and permitted the trial to proceed to the next planned dosing cohort of 3,000mg at a 15-minute infusion rate. More recently, 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. We expect Recce to report results from this cohort shortly.

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 (either towards year-end CY23 or in Q1 CY24) with likely readouts (including ex-vivo analysis) in Q2 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 (a more specific timing projection than our prior estimate of 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 now anticipate the start of such pivotal sepsis studies (in Europe and the United States) in H2 CY25 (versus CY25 previously) and we maintain our estimate for potential approval and commercialisation in sepsis in H2 CY28.

Financials: Raise extends runway into CY24

Recce's FY23 results (year ending 30 June 2023) were largely in line on a cash flow basis with our most recent forecasts, published following the company's Q423 update in July. Net receipts from the Australian Taxation Office were A$4.3m, which were recorded as FY23 revenue, and we believe this came in below our A$6.2m revenue projection due to differences in revenue recognition timing (as the A$1.9m advance payment from Radium Capital was not recognised as part of FY23 revenue). Largely compensating for this variance, net R&D expenses of A$7.3m came in below our A$10.5m estimate. All in, Recce reported a normalised operating loss of A$12.7m (vs A$10.8m in FY22), mildly above our A$12.2m estimate. The main driver for the higher-than-expected loss was higher SG&A costs (A$9.8m, up 27% y-o-y) versus our forecasts (A$8m), with the year-on-year increase largely attributed to higher payroll costs (A$3.6m, up 78% y-o-y). Net operating cash outflows were A$12.7m, slightly better than our A$13.3m forecast. Recce finished FY23 with A$1.56m gross cash and A$3.05m in gross debt (A$1.49m net debt). The company also recently provided a Q124 financial update (for the three months ending 30 September), where it reported a quarterly operating cash burn rate of A$4.2m (driven by A$2.8m in R&D payments). In addition to proceeds from the A$10.7m equity offering completed in September (offset by A$0.48m in transaction costs), financing cash flows were boosted by an A$0.8m loan (advance payment) from Radium Capital. This advance payment represents an accountant-verified proportion of anticipated tax credits relating to March to May 2023 applicable R&D expenditures. The company ended 30 September with a gross cash position of A$8.36m, and we estimate Q124 gross debt of A$3.85m. We calculate pro forma net cash of A$4.8m (which includes the post-period A$0.3m shortfall equity issuance from October).

Following the FY23 results and Q124 update, we have increased our SG&A expenditure forecasts for FY24 by A$2m. As we now expect costs for the US Phase II multi-dose UTI/urosepsis study to only start ramping up materially in H2 CY24 (H1 FY25), we have reduced our FY24 R&D expenditure forecast to A$25.8m (vs A$32.8m previously). We continue to expect R&D spending to increase year-on-year 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 a trial

would reduce our funding estimates over this period but may push back our potential launch forecast in sepsis (currently H2 CY28).

We have reduced our FY24 R&D tax credit revenue forecast to A$3.2m (from A$4.6m) given the lower-than-anticipated FY23 R&D expenses. Altogether we now anticipate an FY24 net operating cash burn rate of A$32.7m, down from A$36.3m previously, and we introduce an FY25 net operating cash burn estimate of A$61.0m. Following the A$11m (gross) raise since early September, we now estimate the company's cash runway lasts into CY24 and model the company will raise A$25m (vs A$37.5m 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. Given the A$11m financing, assuming the company continues to develop all four planned clinical-stage indications, we now assume Recce would need to raise an additional A$225m (vs A$230m 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 a risk-adjusted net present value (rNPV) for Recce, applying a 12.5% discount rate to its four primary development programmes. Aside from adjustments to near-term 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$0.66:US$, versus A$0.64:US$ previously) we obtain a new rNPV valuation, inclusive of A$4.8m estimated pro forma net cash as of 30 September 2023, of A$551.1m (or A$2.71 per share), versus A$562.4m (or A$3.15 per share) previously, with the minor decrease in rNPV driven by the strengthening of the Australian dollar versus the US dollar. The decrease per share was also due to the increased number of shares outstanding following the recent financings.

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$225m is raised through equity issuances at the prevailing market price of c A$0.45, our effective value per share would decrease to A$1.10.

Exhibit 3: 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	3,545	3,857	15%	551	2.71
R327 (IV)	Complicated UTI	CY29	381	411	15%	47	0.23
R327 (topical)	Burn wounds	CY28	271	245	20%	35	0.17
R327 (topical)	Diabetic foot infections	CY29	126	116	15%	7	0.03
Corporate costs				(93.6)		(93.6)	(0.46)
Pro forma estimated net cash at 30 September 2023				4.8		4.8	0.02
Total equity value						551.1	2.71

Source: Edison Investment Research

Exhibit 4: Financial summary

A$(000)	2020	2021	2022	2023	2024e	2025e
Year end 30 June	IFRS	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS						
Revenue	1,122	1,857	3,085	4,311	3,188	10,875
Cost of Sales	0	0	0	(0)	(0)	(0)
Gross Profit	1,122	1,857	3,085	4,311	3,188	10,875
Sales, General & Administrative	(3,136)	(9,511)	(7,677)	(9,779)	(9,964)	(10,402)
Net Research & Development	(2,071)	(5,657)	(6,285)	(7,330)	(25,000)	(55,682)
EBITDA	(4,085)	(13,311)	(10,878)	(12,797)	(31,776)	(55,209)
Depreciation & amortisation of intangible assets	0	0	0	0	0	0
Depreciation, amortisation & other	(201)	(296)	(188)	(217)	(220)	(333)
Normalised Operating Profit (ex. amort, SBC, except.)	(4,231)	(8,389)	(10,809)	(12,689)	(31,996)	(55,542)
Operating profit before exceptionals	(4,286)	(13,607)	(11,065)	(13,014)	(31,996)	(55,542)
Exceptionals including asset impairment	0	0	0	54	0	0
Other	0	0	0	0	0	0
Reported Operating Profit	(4,286)	(13,607)	(11,065)	(12,960)	(31,996)	(55,542)
Net Finance income (costs)	(31)	94	79	(117)	(950)	(5,762)
Profit Before Tax (norm)	(4,317)	(13,513)	(10,986)	(13,131)	(32,946)	(61,304)
Profit Before Tax (FRS 3)	(4,317)	(13,513)	(10,986)	(13,077)	(32,946)	(61,304)
Tax	0	0	0	0	0	0
Profit After Tax and minority interests (norm)	(4,317)	(13,513)	(10,986)	(13,131)	(32,946)	(61,304)
Profit After Tax and minority interests (FRS 3)	(4,317)	(13,513)	(10,986)	(13,077)	(32,946)	(61,304)
Average Basic Number of Shares Outstanding (m)	127.2	155.4	174.1	174.0	191.2	204.2
EPS - normalised (A$)	(0.03)	(0.09)	(0.06)	(0.08)	(0.17)	(0.30)
EPS - normalised and fully diluted (A$)	(0.03)	(0.09)	(0.06)	(0.08)	(0.17)	(0.30)
EPS - (IFRS) (A$)	(0.03)	(0.09)	(0.06)	(0.08)	(0.17)	(0.30)
Dividend per share (A$)	0.0	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET						
Fixed Assets	505	501	439	608	547	387
Intangible Assets	0	0	0	0	0	0
Tangible Assets	505	501	439	608	547	387
Investments in long-term financial assets	0	0	0	0	0	0
Current Assets	2,739	21,181	12,185	1,947	4,720	8,575
Short-term investments	0	0	0	0	0	0
Cash	2,682	20,873	11,582	1,562	4,334	8,190
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)	(25,295)	(90,295)
Long term borrowings	0	0	0	0	(25,000)	(90,000)
Other long term liabilities	(46)	(100)	(115)	(295)	(295)	(295)
Net Assets	2,313	20,504	10,061	(2,589)	(24,878)	(86,182)
CASH FLOW STATEMENT						
Operating Income	(4,286)	(13,607)	(11,065)	(12,960)	(31,996)	(55,542)
Movements in working capital	253	144	1,532	(152)	0	0
Net interest and financing income (expense)	(31)	94	79	(117)	(950)	(5,762)
Depreciation & other	201	296	188	217	220	333
Taxes and other adjustments	55	5,218	256	325	0	0
Net Cash Flows from Operations	(3,807)	(7,856)	(9,010)	(12,687)	(32,726)	(60,970)
Capex and capitalised expenditures	(6)	(76)	(40)	(39)	(158)	(174)
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)	(158)	(174)
Net proceeds from share issuances	6,980	26,338	287	102	10,656	0
Net movements in long-term debt	0	0	0	0	25,000	65,000
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	35,656	65,000
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)	2,772	3,856
Cash & equivalents at beginning of period	403	2,682	20,873	11,582	1,562	4,334
Cash & equivalents at end of period	2,682	20,873	11,582	1,562	4,334	8,190
Closing net debt/(cash)	(2,682)	(20,873)	(11,582)	1,487	23,714	38,129
Lease debt	83	127	75	251	251	251
Closing net debt/(cash) inclusive of IFRS16 lease debt	(2,599)	(20,746)	(11,507)	1,737	23,965	38,379
Free cash flow	(3,813)	(7,932)	(9,051)	(12,726)	(32,884)	(61,144)

Source: company accounts, Edison Investment Research

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London | New York | Frankfurt
20 Red Lion Street
London, WC1R 4PS
United Kingdom