EDISON

Recce Pharmaceuticals

Financing update

R&D advance (A$11.18m) extends runway

Healthcare

Recce Pharmaceuticals recently received A$11.18m as an R&D advance credit through an arrangement with Endpoints Capital for the R&D tax credit rebates that Recce expects to receive for FY23/FY24 and FY25. We believe this non-dilutive source of funding should extend Recce's operating runway into FY25. Recce is also continuing to advance its intravenous (IV) R327 formulation in its ongoing Phase I/II study in healthy volunteers, having recently started the 20-minute (3,000mg) dosing cohort. We have made minor adjustments to our valuation and we now obtain a risk-adjusted net present value (rNPV) of A$644.4m (or A$3.16/share), versus A$652.6m 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	5.8	(18.1)	(0.09)	0.0	N/A	N/A
06/25e	6.7	(58.4)	(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.

Rapid infusion IV R327 study moves to next cohort

Recce's priority is to advance the 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 in March 2024, Recce confirmed that the 3,000mg dose administered at varying infusion times between 15 and 60 minutes was shown to be safe. The study's independent safety committee (ISC) also cleared the study to proceed to the next dosing infusion level of 3,000mg within a 20-minute interval, and we understand that the first subjects of this (20-minute) cohort have now been dosed, with the rest expected to be dosed over the coming weeks. 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 H2 CY24.

DFI study receives clearance to expand study sites

Following positive efficacy results reported in January among five patients treated in its Phase I/II study of topical R327 in patients with diabetic foot infections (DFI), the company received approval in February 2024 from the trial's independent safety committee to expand this programme to additional domestic and global sites. Recce plans to open additional sites over the coming months, which we anticipate will include countries in South-East Asia through its strategic partnership with PT Etana Biotechnologies.

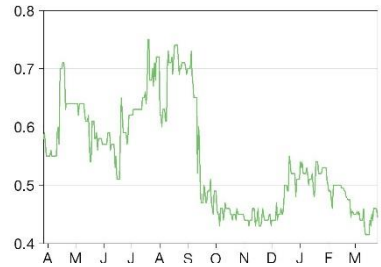
Valuation: Minor adjustments bring rNPV to A$644.4m

We continue to determine an rNPV for Recce, applying a 12.5% discount rate to its four primary development programmes. Our core valuation and modelling assumptions are essentially unchanged. Following minor adjustments (discussed below), we now obtain a new rNPV valuation, inclusive of A$1.8m H124 net cash as of 31 December 2023, of A$644.4m (or A$3.16 per share), versus A$652.6m (or A$3.20 per share) previously.

26 March 2024

Price	**A$0.48**
Market cap	**A$98m**
	US$0.65/A$
Net cash (A$m) at 31 December 2023	1.8
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	0.0	(14.4)	(19.8)
Rel (local)	(2.1)	(18.0)	(29.1)
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	H2 CY24

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Edison profile page

A$11.18m R&D advance lengthens funding runway

Recce recently announced that it received 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. For FY23 (the period ending June 2023), Recce had already received A$2.28m from the Australian government as a R&D expenditure rebate in November 2023 (the first of three expected tranches); it expects to receive a second tranche of A$3.04m in Q1 CY24 and the third tranche of A$0.35m in Q2 CY24. The R&D advance credit from Endpoints does not entail or result in any share dilution and accrues interest at 15% per year. It can be repaid as the company receives R&D rebates through the relevant Australian tax authorities.

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 continue to 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. Recce is advancing R327 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.

The company reports that it expects this funding advance from Endpoints to not only extend its runway, but to also help accelerate its multiple clinical programmes.

We previously assumed that Recce's cash on hand would last into Q2 CY24, but with this advance credit, we now believe the company will be funded into Q3 CY24 or FY25 (as detailed in the Financials section below).

Phase I/II IV R327 rapid infusion study advances to next cohort

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). Recce 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 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. Most recently, in March 2024, Recce confirmed that the 3,000mg dose administered at varying infusion times between 15 and 60 minutes was shown to be safe. The ISC also cleared the study to proceed to the next dosing infusion level of 3,000mg within a 20-minute interval; we understand that the first subjects of this (20-minute) cohort have now been dosed, with the remainder expected to be dosed over the coming weeks. 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 clinical studies for IV R327 in UTIs and/or urosepsis.

We expect Recce to submit an Investigational New Drug application to the US FDA and then start a multiple-dose global (ie including US sites) Phase II efficacy study in UTIs/urosepsis in H2 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.

Topical R327 DFI study to expand after positive ISC review

In February 2024 Recce announced that the ISC for its ongoing Phase I/II study assessing topical R327 in skin and soft tissue DFIs unanimously agreed to expand the study based on an interim analysis of the patients that had been treated to date. The ISC at Liverpool Hospital NSW reviewed all the data to date of 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).

As a reminder, Recce first announced in January 2024 that the results to date from this study (discussed in further detail in our prior note) had met all primary endpoints and it was working to expand the study both domestically and internationally. With the ISC now allowing for study expansion, Recce can proceed with adding clinical trial sites both in Australia and internationally, for the treatment of DFIs with topical R327. The company expects to include additional study sites in the coming months.

We anticipate Recce will likely consider study sites in Indonesia and other ASEAN member state countries (which collectively cover 670 million individuals) given the company's recently announced strategic partnership and MoU in South-East Asia with Indonesian biomedical company Etana. The MoU is designed to facilitate the development, assessment and potential commercialisation of Recce's broad-spectrum antimicrobial compounds and 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.

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 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 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.

Financials: Raise extends runway into late FY24

Recce reported H124 financial results, which are generally consistent with the 4C quarterly cash flow statement (for the quarter ending 31 December 2023, or fiscal Q224). The company reported an H124 operating cash burn rate of A$6.5m, in line with our estimates, and ended the period with a gross cash position of A$4.0m. Recce received a A$2.28m R&D incentive rebate from the Australian government in November 2023 and used part of the proceeds to pay its R&D advance credit liability to Radium Capital, which was recorded at A$2.23m at 31 December (down from A$3.05m at 30 June). Altogether, we calculate H124 net debt at A$1.8m.

We have updated our model to reflect the A$11.18m advance payment received from Endpoints and have reduced our FY24 R&D expense assumptions (to A$15.4m, from A$20.0m previously) as we now expect more of the early costs for the projected multiple-dose Phase II efficacy study in UTIs/urosepsis to be incurred in FY25. We have kept our FY25 and medium-term operating cost assumptions largely unchanged. We have also adjusted our H224 estimates to reflect the additional R&D rebate tranches Recce expects to receive (totalling A$3.4m) from the Australian government in H224 (H1 CY24), although we model that these proceeds will be used to pay the liability to Endpoints. We continue to expect that the company will receive R&D tax credit proceeds (or grants) at 43.5% of prior-year R&D expenditure levels.

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 we anticipate increasing costs for the DFI programme with global trial site engagement. 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.

We now anticipate FY24 and FY25 net operating cash burn rates of A$16.9m (down from A$24.7m previously) and A$58.2m (up from A$54.9m previously). The primary driver for the increase in FY25 is the increased assumptions for the cost of debt (given the 15% pa cost of the Endpoints liability).

Given the advance credit from Endpoints, we now estimate Recce's cash runway lasts into FY25 (Q3 CY24), versus Q2 CY24 previously. We model that the company will raise A$60m in FY25.

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 now assume Recce would need to raise an additional A$200m (vs A$205m previously) 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.

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. Our core valuation and modelling assumptions are essentially unchanged (see our initiation note for details). Given the minor adjustments described above, we now obtain a new rNPV valuation, inclusive of A$1.8m H124 net cash as of 31 December 2023, of A$644.4m (or A$3.16 per share), versus A$652.6m (or A$3.20 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$0.45, our effective value per share would decrease to A$1.30 (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	4,175	15%	614	3.01
R327 (IV)	Complicated UTI	CY29	387	448	15%	55	0.27
R327 (topical)	Burn wounds	CY28	275	269	20%	42	0.21
R327 (topical)	DFI	CY29	128	125	15%	8	0.04
Corporate costs				(75.6)		(75.6)	(0.37)
Net cash (debt) at 31 December 2023				1.8		1.8	0.01
Total equity value						**644.4**	**3.16**

Source: Edison Investment Research

Exhibit 2: Financial summary

A$(000)	2020	2021	2022	2023	2024e	2025e
Year end 30 June	IFRS	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS						
Revenue	1,122	1,857	3,085	4,311	5,771	6,692
Cost of Sales	0	0	0	(0)	(0)	(0)
Gross Profit	1,122	1,857	3,085	4,311	5,771	6,692
Sales, General & Administrative	(3,136)	(9,511)	(7,677)	(9,779)	(7,591)	(8,078)
Net Research & Development	(2,071)	(5,657)	(6,285)	(7,330)	(15,385)	(51,154)
EBITDA	(4,085)	(13,311)	(10,878)	(12,797)	(17,204)	(52,540)
Depreciation & amortisation of intangible assets	0	0	0	0	0	0
Depreciation, amortisation & other	(201)	(296)	(188)	(217)	(380)	(283)
Normalised Operating Profit (ex. amort, SBC, except.)	(4,231)	(8,389)	(10,809)	(12,689)	(17,585)	(52,823)
Operating profit before exceptionals	(4,286)	(13,607)	(11,065)	(13,014)	(17,585)	(52,823)
Exceptionals including asset impairment	0	0	0	54	0	0
Other	0	0	0	0	0	0
Reported Operating Profit	(4,286)	(13,607)	(11,065)	(12,960)	(17,585)	(52,823)
Net Finance income (costs)	(31)	94	79	(117)	(471)	(5,620)
Profit Before Tax (norm)	(4,317)	(13,513)	(10,986)	(13,131)	(18,056)	(58,443)
Profit Before Tax (FRS 3)	(4,317)	(13,513)	(10,986)	(13,077)	(18,056)	(58,443)
Tax	0	0	0	0	0	0
Profit After Tax and minority interests (norm)	(4,317)	(13,513)	(10,986)	(13,131)	(18,056)	(58,443)
Profit After Tax and minority interests (FRS 3)	(4,317)	(13,513)	(10,986)	(13,077)	(18,056)	(58,443)
Average Basic Number of Shares Outstanding (m)	127.2	155.4	174.1	174.0	191.0	203.7
EPS - normalised (A$)	(0.03)	(0.09)	(0.06)	(0.08)	(0.09)	(0.29)
EPS - normalised and fully diluted (A$)	(0.03)	(0.09)	(0.06)	(0.08)	(0.09)	(0.29)
EPS - (IFRS) (A$)	(0.03)	(0.09)	(0.06)	(0.08)	(0.09)	(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	463	321
Intangible Assets	0	0	0	0	0	0
Tangible Assets	505	501	439	608	463	321
Investments in long-term financial assets	0	0	0	0	0	0
Current Assets	2,739	21,181	12,185	1,947	2,206	3,905
Short-term investments	0	0	0	0	0	0
Cash	2,682	20,873	11,582	1,562	1,370	3,070
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)	(8,081)	(68,081)
Long term borrowings	0	0	0	0	(7,790)	(67,790)
Other long term liabilities	(46)	(100)	(115)	(295)	(291)	(291)
Net Assets	2,313	20,504	10,061	(2,589)	(10,060)	(68,503)
CASH FLOW STATEMENT						
Operating Income	(4,286)	(13,607)	(11,065)	(12,960)	(17,585)	(52,823)
Movements in working capital	253	144	1,532	(152)	751	0
Net interest and financing income (expense)	(31)	94	79	(117)	(471)	(5,620)
Depreciation & other	201	296	188	217	380	283
Taxes and other adjustments	55	5,218	256	325	0	0
Net Cash Flows from Operations	(3,807)	(7,856)	(9,010)	(12,687)	(16,925)	(58,160)
Capex and capitalised expenditures	(6)	(76)	(40)	(39)	(128)	(140)
Acquisitions/disposals	0	0	0	0	(34)	0
Interest received & other investing activities	0	0	0	0	0	0
Net Cash flows from Investing activities	(6)	(76)	(40)	(39)	(161)	(140)
Net proceeds from share issuances	6,980	26,338	287	102	10,585	0
Net movements in long-term debt	0	0	0	0	6,310	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	16,895	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)	(192)	1,699
Cash & equivalents at beginning of period	403	2,682	20,873	11,582	1,562	1,370
Cash & equivalents at end of period	2,682	20,873	11,582	1,562	1,370	3,070
Closing net debt/(cash)	(2,682)	(20,873)	(11,582)	1,487	8,653	22,120
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	8,852	22,318
Free cash flow	(3,813)	(7,932)	(9,051)	(12,726)	(17,086)	(58,301)

Source: Company accounts, Edison Investment Research

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