EDISON

Recce Pharmaceuticals

R327 study update

R327 progressing in rapid infusion study

Healthcare

Recce recently reported the completion of its data review from its earlier long-infusion Phase I study of the intravenous (IV) RECCE 327 (R327) formulation, confirming that the drug candidate shows favourable safety characteristics, a robust dose-dependent pharmacokinetic drug concentration response, as well as evidence of increased drug concentration into the urinary tract. The company is proceeding with a Phase I/II study assessing using a more rapid infusion rate, with recent completion of the first 2,500mg cohort of the Phase I part ahead of schedule. Obtaining financing is a near-term strategic priority given the cash at hand (A$1.6m at 30 June 2023), and the company's current cash runway is short (into late Q3 CY23). Recce has signalled that it is seeking to raise A$12–15m. After rolling forward our estimates and updating forex assumptions, we obtain an rNPV valuation of A$562.4m (or A$3.15 per share), up from A$535.6m previously.

Year end	Revenue (A$m)	PBT* (A$m)	EPS* (A$)	DPS (A$)	P/E (x)	Yield (%)
06/21	1.9	(13.5)	(0.09)	0.0	N/A	N/A
06/22	3.1	(11.0)	(0.06)	0.0	N/A	N/A
06/23e	6.2	(12.4)	(0.07)	0.0	N/A	N/A
06/24e	4.6	(36.5)	(0.20)	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 study tracking well

The Phase I part of the IV R327 study will assess faster infusion rates of R327 in c 16 healthy participants across three cohorts, with the company recently reporting that R327 was safe and well-tolerated at a 2,500mg dose level when administered at two faster infusion rates (the durations of the tested infusion rates are not yet specified) and that dosing was completed ahead of schedule. An Independent Safety Committee is reviewing cohort data and the company expects the committee to permit the study to move on to the next planned dosing cohort, and recruitment is reported to be proceeding well. Based on the results from the Phase I portion of the trial, optimal dosing levels and infusion rates will be decided for the Phase II portion, which will be conducted in patients with uncomplicated or recurrent UTIs. We expect the Phase II part of the study to also commence in H2 CY23 with likely readouts around year-end CY23. We expect insights from this study to influence the design of the planned Phase II trial in urosepsis in CY24 (c 25% of all sepsis cases are caused by UTIs).

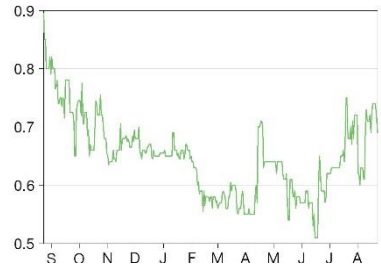
Valuation: Mild revision to A$562m

We have deferred some of our projected R&D costs into FY25 and FY26 given the currently challenging capital markets environment and have pushed back our launch timing estimate for R327 in sepsis by around six months to H2 CY28. We now model that the company will raise A$37.5m in total funding (down from A$55m previously) before the end of FY24. After rolling our model forward and updating our forex assumptions, we obtain an rNPV valuation of A$562.4m (or A$3.15 per share), up from A$535.6m previously, with the decrease in the value of the Australian dollar the primary driver of the increased valuation.

23 August 2023

Price	**A$0.69**
Market cap	**A$123m**
	US$0.64/A$
Gross cash (A$m) at 30 June 2023	1.6
Shares in issue	178.3m
Free float	56.4%
Code	RCE
Primary exchange	ASX
Secondary exchanges	Frankfurt: R9Q, OTC: RECEF

Share price performance



%	1m	3m	12m
Abs	1.5	19.0	(20.7)
Rel (local)	4.0	20.7	(21.3)
52-week high/low		A$0.9	A$0.5

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.

Next events

Start Phase II R327 (IV) study in urinary tract infections	H2 CY23
Interim results from topical R327 studies in DFI	H2 CY23

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Edison profile page

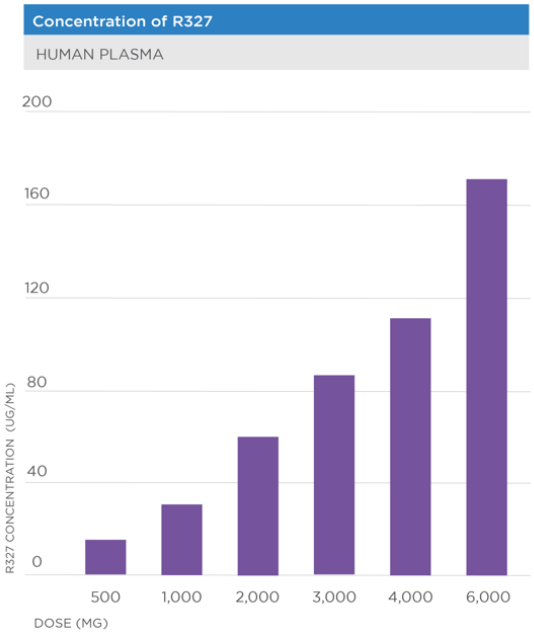
Positive final data from long-infusion IV R327 study

Recce in July 2023 reported the completion of its data review for the previous single dose-escalation Phase I trial 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.

In August 2022, the company reported that in this study R327 was well-tolerated at a one-hour IV dose up to 6,000mg with no serious adverse events (SAEs) in a cohort of 10 patients at that dosing range. The company has now provided more complete data showing favourable safety characteristics, a robust dose-dependent PK drug concentration response, as well as evidence of increased drug concentration into the urinary tract, potentially making the drug candidate suitable for urinary tract infections (UTIs) and urosepsis.

In the study, the drug was found to be safe and well-tolerated and there were no SAEs 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 and 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

Another positive finding from the study was that 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 moving ahead of schedule in rapid infusion trial

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, having received in April 2023 approval from a Human Research Ethics committee (HREC) to conduct this study in healthy volunteers. The rationale for now assessing R327 at faster infusion rates is the potential benefit of providing broader access to the drug in primary care and acute patient care settings.

The company received approval in June 2023 from the HREC to expand this study to include the Scientia Clinical Research site (Sydney) as well as the CMAX Clinical Research facility in Adelaide, which is where the one-hour R327 infusion study was held.

The Phase I portion of this IV safety study is evaluating faster infusions of R327 in c 16 participants, across three cohorts. Plasma and urine samples are being collected at various time points during and following dosing to evaluate the drug's concentrations and its antibacterial effect in the urine on various bacterial strains. The company announced in July that the first cohort (including both male and female subjects) in this rapid infusion study was safely and successfully dosed 2,500mg of R327. Subsequently, the company reported 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) and that dosing was completed ahead of schedule. An Independent Safety Committee is reviewing cohort data and the company expects the committee to permit the study to move on to the next planned dosing cohort, and recruitment is reported to be proceeding well.

Based on the results from the Phase I portion of the trial, optimal dosing levels and infusion rates will be decided for the Phase II portion, which will be conducted in patients with uncomplicated or recurrent UTIs. We expect the Phase II part of the study to also commence in H2 CY23, with likely readouts around year-end CY23.

If results are positive, we expect Recce to submit an Investigational New Drug application to the US FDA and then start a separate multiple-dose Phase II efficacy study in urosepsis in 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. While company guidance has been for a Phase III sepsis study on the IV drug formulation to start in H2 CY24, we anticipate the start of such pivotal sepsis studies (in Europe and the United States) in CY25 and, if the drug is approved, for it to be commercialised in CY28.

R327 gel may boost Recce's topical offering

Recce recently reported that a qualified Australian medical practitioner has been treating certain antibiotic-resistant Gram-positive and Gram-negative bacterial skin infections with a proprietary gel formulation of R327 (R327G) under a Special Access Scheme in Australia (SAS-Category A) reserved for patients who are seriously ill with a condition that may result in death in the absence of effective treatment. R327G is not being studied in any of the company's current clinical trials, but the company has reported anecdotal findings where the drug provided benefit, including a 70–75 year-old male suffering from a puncture wound from a metal spike injury, which had previously been unresponsive to all prior antibiotics and the infection had been spreading and the patient had been prepared for surgical intervention. With only a single dosing application of R327G, the infection had clinically responded (without requiring pre-treatment wound debridement) and as of 30 days post-treatment, the wound had healed and closed.

The company also reported a case of a 72-year-old male with Type 2 diabetes who had a diabetic foot infection that had been unresponsive to prior treatment. Following R327G application, the infection had resolved with significant improvement by day 14 post-treatment and surgical intervention (ie amputation) was averted. The company also reports that R327G had been successful in treating human cases of necrotising fasciitis, osteomyelitis and complex skin structure bacterial infections (SSTIs). However, as these cases were not reported within the context of a controlled study, there are limitations in interpreting the significance of the data, and there is no information on whether there were cases which R327G may not have been successful (and how many if so).

R327G had been assessed by an independent CRO in animal studies and had shown in an ex-vivo pig skin model that within 24 hours it resulted in a 4–5 log reduction (99.99% to 99.999%) in bacterial counts of methicillin-resistant *Staphylococcus aureus* (MRSA), a leading cause of hospital-acquired infections that is associated with significant morbidity, mortality and disease burden. Based on the animal data and the encouraging anecdotal cases cited above, the company is working with its collaborators (including the burn wound team at Fiona Stanley Hospital in Australia) to potentially advance clinical studies involving topical R327G for common and complicated SSTIs. While we view this advancement as promising, we are not revising our estimates at this time to reflect the potential of R327G in SSTIs, but may do so once there is greater clarity on a potential clinical pathway.

Sponsored Burn wound study moving to Stage 2

Recce provided an update regarding its Phase I/II trial for topical (spray-on) R327 in burn wound infections, sponsored by the West Australian health department and conducted at Fiona Stanley Hospital. The non-randomised Phase I/II R327 spray formulation study was first designed to enrol up to 30 patients with clinical signs and symptoms of local burn wound infection. Over a 14-day treatment period, patients would be randomised to receive topical R327 daily or to receive the drug three times per week. The company has reported that clinicians have observed a visible reduction in bacterial infection within 24 hours of topical R327 treatment, demonstrating broad spectrum antibacterial activity, as well as positive indications of safety and tolerability. The company notes that due to difficulty in recruiting appropriate patients (due primarily to COVID-19 protocols including antibiotic infection control practices), the initially planned study protocol (termed Stage 1) has concluded, as many of the screened patients did not meet study protocol requirements (due to the need for no prior antibiotic treatment prior to enrolment).

The study investigators remain interested in further assessing the R327 drug candidate and are preparing a new protocol for Stage 2, which is expected to be a randomised head-to-head study in patients with infected burn wounds, comparing the new gel formulation described above (R327G) to existing treatment standard-of-care. We await further updates as to when the Stage 2 portion of the study, which will now assess R327G, will begin enrolment.

Topical R327 DFI studies are underway

In December 2022, Recce received Australian approval to start an open-label Phase I/II study at the South West Sydney Limb Preservation and Wound Research Unit of a topical R327 formulation, which differs from R327G (which is a gel), for mild diabetic foot infections (DFIs). The study will assess R327 in this indication in up to 32 patients with mild skin and soft tissue DFIs, where patients will receive R327 daily for 14 days. In August 2023, the company announced that patient dosing has commenced and that it expects to report results later in Q3 CY23.

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 experience foot ulceration each year, of which 50–60% will result in DFIs, the leading cause of foot morbidity in diabetic patients. Recce believes that topical R327 could potentially be useful in mild DFIs (as more advanced cases require systemic antibiotics).

While current literature suggests that topical application of antimicrobials may have merit in many cases (such as patients who do not tolerate oral antibiotics), current 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 current Australian Phase II study is successful, we assume the company would pursue a second Phase II study in CY24 that would include multiple sites (including the United States and/or Europe) before starting a Phase III pivotal programme in CY25, which we model could lead to launch in CY29.

Financials: Funding raise expected shortly

Recce reported A$1.6m in gross cash at 30 June 2023, and subsequently received another A$0.8m advance from Radium Capital in early July 2023 (which corresponds to a portion of the anticipated R&D tax credit that the company expects to receive in FY24 for FY23 activities). In FY23, the company received A$2.88m in advances from Radium Capital. These advances all correspond to advance payments for R&D tax credits and they are expected to be repaid once R&D tax credit cash inflows are received by Recce from the Australian government.

Primary cash outflows during Q423 were related to R&D (A$2.4m) and staff and admin expenses (A$0.9m). Its overall operating cash burn rate was A$13.3m in FY23, which includes A$4.4m in government grants and tax incentives (excluding such effects, the cash outflow rate would have been A$17.7m). While we expect the company to continue to benefit from Australia's 43.5% R&D refundable tax credit, we expect operating costs to rise in coming years, due to anticipated larger-scale Phase II and Phase III studies required for each of the four sought indications in our model (sepsis, UTIs, DFI and burn wounds).

We estimate Recce's current cash on hand will fund operations into late Q3 CY23, and the company has indicated that it is working to secure A$12–15m in additional funding and will update the market at the appropriate time.

We have reduced our FY24 R&D expenditure expectations as we are deferring some of our projected clinical study funding needs into FY25 and FY26 given the currently challenging capital markets environment (for development-stage life science companies). Given these deferrals, we are pushing back our expected launch timing estimate for R327 in sepsis by around six months, from CY28 to H2 CY28. We now anticipate a net operating cash burn rate of A$36m in FY24 (vs A$42m previously) and A$67m in FY25 (vs A$65m previously).

Given our reduced near-term expenditure expectations, we now model that the company will raise A$37.5m in total funding (down from A$55m previously) before the end of FY24.

A significant driver of the year-on-year increase in our operating expense assumptions in FY24 and again in FY25 is our projection that the company will start a multiple-dose Phase II efficacy study in urosepsis in CY24 that includes multiple US sites. Any delays to the start of such a trial would reduce our funding estimates over this period, but may also push back our potential launch forecast in sepsis (currently H2 CY28).

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 complicated UTIs (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 assume Recce would need to raise A$230m in total by FY29 before becoming sustainably cash flow positive. This is mildly higher than our prior A$220m estimate, with the increase largely due to the pushing back of our estimate for the R327 launch in sepsis to H2 CY28 (and the resulting need for the company to cover SG&A and operating costs over a longer period without operating revenues from R327 in sepsis). 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 it may terminate the ATM 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 deferring near-term R&D costs and pushing our R327 in sepsis launch forecast to H2 CY28, as described above, our core valuation and modelling assumptions are unchanged – please see our initiation note for details. We have rolled forward our model, updated our forex estimates (A$0.64/US$ vs A$0.67/US$ previously) and the net debt estimate (to A$1.3m net debt at Q423, to reflect the A$1.6m gross cash and A$2.9m estimated liability to Radium Capital). Following these changes, we obtain a new rNPV valuation of A$562.4m (or A$3.15 per share), up from A$535.6m previously, with the decrease in

the value of the Australian dollar the primary driver for the increased valuation (as the translation of future expected US revenue increases in value in terms of Australian dollars. If we assume an A$/US$ exchange rate identical to that in our prior note (A$0.67/US$), the resulting valuation would be A$533.3m, or A$2.99 per basic share.

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$230m is raised through equity issuances at the prevailing market price of c A$0.70, our effective value per share would decrease to A$1.56.

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	3,656	3,976	15%	564	3.16
R327 (IV)	Complicated UTI	2029	393	422	15%	47	0.26
R327/R327G (topical)	Burn wounds	2028	280	250	20%	34	0.19
R327 (topical)	Diabetic foot infections	2029	130	117	15%	5	0.03
Corporate costs				(86.1)		(86.1)	(0.48)
Estimated net cash/(debt) at 30 June 2023				(1.3)		(1.3)	(0.01)
Total equity value						562.4	3.15

Source: Edison Investment Research

Exhibit 4: Financial summary

A$(000)	2020	2021	2022	2023e	2024e
Year end 30 June	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue	1,122	1,857	3,085	6,219	4,586
Cost of Sales	0	0	0	(0)	(0)
Gross Profit	1,122	1,857	3,085	6,219	4,586
Sales, General & Administrative	(3,136)	(9,511)	(7,677)	(7,997)	(8,055)
Net Research & Development	(2,071)	(5,657)	(6,285)	(10,542)	(32,813)
EBITDA	(4,085)	(13,311)	(10,878)	(12,319)	(36,282)
Depreciation & amortisation of intangible assets	0	0	0	0	0
Depreciation, amortisation & other	(201)	(296)	(188)	(180)	(175)
Normalised Operating Profit (ex. amort, SBC, except.)	(4,231)	(8,389)	(10,809)	(12,174)	(36,456)
Operating profit before exceptionals	(4,286)	(13,607)	(11,065)	(12,499)	(36,456)
Exceptionals including asset impairment	0	0	0	0	0
Other	0	0	0	0	0
Reported Operating Profit	(4,286)	(13,607)	(11,065)	(12,499)	(36,456)
Net Finance income (costs)	(31)	94	79	56	(51)
Profit Before Tax (norm)	(4,317)	(13,513)	(10,986)	(12,443)	(36,508)
Profit Before Tax (FRS 3)	(4,317)	(13,513)	(10,986)	(12,443)	(36,508)
Tax	0	0	0	0	0
Profit After Tax and minority interests (norm)	(4,317)	(13,513)	(10,986)	(12,443)	(36,508)
Profit After Tax and minority interests (FRS 3)	(4,317)	(13,513)	(10,986)	(12,443)	(36,508)
Average Basic Number of Shares Outstanding (m)	127.2	155.4	174.1	177.5	178.3
EPS - normalised (A$)	(0.03)	(0.09)	(0.06)	(0.07)	(0.20)
EPS - normalised and fully diluted (A$)	(0.03)	(0.09)	(0.06)	(0.07)	(0.20)
EPS - (IFRS) (A$)	(0.03)	(0.09)	(0.06)	(0.07)	(0.20)
Dividend per share (A$)	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET					
Fixed Assets	505	501	439	454	316
Intangible Assets	0	0	0	51	51
Tangible Assets	505	501	439	402	264
Investments in long-term financial assets	0	0	0	0	0
Current Assets	2,739	21,181	12,185	1,873	3,003
Short-term investments	0	0	0	0	0
Cash	2,682	20,873	11,582	1,562	2,692
Other	57	308	603	311	311
Current Liabilities	(885)	(1,078)	(2,447)	(4,047)	(4,047)
Creditors	(885)	(1,078)	(2,447)	(1,168)	(1,168)
Short term borrowings	0	0	0	(2,880)	(2,880)
Long Term Liabilities	(46)	(100)	(115)	(233)	(37,733)
Long term borrowings	0	0	0	0	(37,500)
Other long term liabilities	(46)	(100)	(115)	(233)	(233)
Net Assets	2,313	20,504	10,061	(1,954)	(38,461)
CASH FLOW STATEMENT					
Operating Income	(4,286)	(13,607)	(11,065)	(12,499)	(36,456)
Movements in working capital	253	144	1,532	126	0
Net interest and financing income (expense)	(31)	94	79	56	(51)
Depreciation & other	201	296	188	180	175
Taxes and other adjustments	55	5,218	256	(1,175)	0
Net Cash Flows from Operations	(3,807)	(7,856)	(9,010)	(13,312)	(36,333)
Capex and capitalised expenditures	(6)	(76)	(40)	(33)	(37)
Acquisitions/disposals	0	0	0	343	0
Interest received & other investing activities	0	0	0	0	0
Net Cash flows from Investing activities	(6)	(76)	(40)	310	(37)
Net proceeds from share issuances	6,980	26,338	287	102	0
Net movements in long-term debt	0	0	0	0	37,500
Dividends	0	0	0	0	0
Other financing activities	(888)	(215)	(528)	2,880	0
Net Cash flows from financing activities	6,092	26,123	(240)	2,982	37,500
Effects of FX on Cash & equivalents	0	0	0	0	0
Net Increase (Decrease) in Cash & equivalents	2,279	18,191	(9,291)	(10,020)	1,130
Cash & equivalents at beginning of period	403	2,682	20,873	11,582	1,562
Cash & equivalents at end of period	2,682	20,873	11,582	1,562	2,692
Closing net debt/(cash)	(2,682)	(20,873)	(11,582)	1,318	37,688
Lease debt	83	127	75	127	127
Closing net debt/(cash) inclusive of IFRS 16 lease debt	(2,599)	(20,746)	(11,507)	1,446	37,815
Free cash flow	(3,813)	(7,932)	(9,051)	(13,002)	(36,370)

Source: Edison Investment Research

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