EDISON

Recce Pharmaceuticals

Indication review

Taking a closer look at diabetic foot infections

Healthcare

We highlight the opportunity of topical RECCE® 327 (R327) to address diabetic foot infections (DFIs), which is the leading cause of limb morbidity in diabetic patients and an area of unmet need as currently available topical drugs have limited effectiveness. Recce is planning to initiate a Phase III registration-enabling study in H2 CY24 in Indonesia. We anticipate that positive results from the trial could lead to Recce's earliest R327 commercialisation opportunity, through a launch in South-East Asia in the DFI indication in H2 CY26. The company announced an A$10m equity financing that is expected to extend its runway into FY26. We now obtain an rNPV valuation of A$688.5m (or A$3.07 per share), versus A$661.3m (or A$3.27 per share) previously. The reduced value per share is due to the anticipated increase in share count post-financing.

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	(17.2)	(0.09)	0.0	N/A	N/A
06/25e	9.6	(14.4)	(0.07)	0.0	N/A	N/A

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

Phase III DFI study accelerates commercial potential

Recce announced in January 2024 that interim data from its Phase I/II study assessing topical R327 in mild skin and soft tissue DFIs met all primary endpoints (including resolving or curing bacterial DFIs) on five patients, providing signs of proof-of-concept for topical R327 in this indication. The company plans to start a Phase III registrational study for topical R327 in DFIs in Indonesia in Q3 CY24. This marks the first major step towards a larger-scale clinical efficacy trial and potential commercialisation. We assume that positive results could lead to commercial launch in Indonesia and other Association of Southeast Asian Nations (ASEAN) member state countries in H2 CY26.

Recce's A$10m financing to extend runway to FY26

Recce is raising A$10m in equity through an institutional placement of A$8m, priced at A$0.45 per share, and an A$2.0m share purchase plan (SPP) to remaining existing shareholders. The majority of proceeds will be directed towards upcoming clinical trial activities and costs relating to filing an investigational new drug (IND) application with the US FDA (to permit US studies for R327). The company expects that in combination with other grants and R&D rebates expected in FY25, this financing will enable it to maintain its operations into FY26 (or H2 CY25).

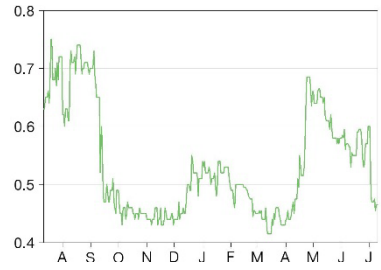
Valuation: Revisions post-financing

Given the FY25 guidance, we have reduced our FY25 R&D expenditure estimates as we now assume that significant involvement of US study sites for R327 clinical trials is unlikely to start until late FY25. We maintain our R327 commercial launch timing estimates and we obtain an rNPV valuation, inclusive of the A$10m financing, of A$688.5m (or A$3.07 per share), versus A$661.3m (or A$3.27 per share) previously. The reduced value per share is due to the anticipated increase in share count (from 204.0m pre-placement to 226.2m) following the A$10m financing.

11 July 2024

Price	**A$0.46**
Market cap	**A$102m**
	US$0.67/A$
Estimated net debt (A$m) at 31 March 2024	3.0
Shares in issue (including shares from A$8m July 2024 placement but not the A$2m SPP)	221.8m
Free float	56.4%
Code	RCE
Primary exchange	ASX
Secondary exchanges	Frankfurt: R9Q, OTC: RECEF

Share price performance



%	1m	3m	12m
Abs	(17.7)	3.3	(25.0)
Rel (local)	(17.1)	4.0	(32.9)
52-week high/low	A$0.75		A$0.41

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

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R327 seeks breakthrough in topical DFI landscape

Recce has reported progress in its lead R327 anti-infective therapeutic programme in recent months. It is advancing the drug candidate as an IV formulation for the treatment of sepsis and for complicated urinary tract infections (cUTIs) and urosepsis, and in topical formulations for DFIs and burn wound infections. In this note we are highlighting the opportunity of R327 to address DFIs, particularly in light of recent developments whereby the company is now planning to initiate a Phase III registration-enabling study in H2 CY24 in Indonesia. We anticipate that positive results from the trial could lead to Recce's earliest R327 commercialisation opportunity, through a launch in South-East Asia in the DFI indication in H2 CY26.

Background on diabetic foot infections

Diabetic foot ulcers are frequent complications of patients who have diabetes mellitus, if the condition is not adequately controlled. Approximately 38 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 due to the invasion and multiplication of surrounding microorganisms into the area, resulting in an inflammatory response and tissue damage. DFIs are the leading cause of foot morbidity in diabetic patients as well as the most frequent complication from diabetes requiring hospitalisation. About 20% of moderate to severe DFIs lead to amputation and diabetes is reported to be the leading cause of non-traumatic lower extremity amputations in the US.

DFIs occur mostly in diabetic patients with peripheral neuropathy and/or peripheral artery disease, as these increase the risk of an ulcer becoming infected. While most DFIs are located at relatively superficial layers upon clinical presentation, the infecting microorganisms can spread to subcutaneous and deeper tissues, such as fascia, tendons, muscles, joints and bones. Generally, targeted systemic (oral or intravenous) antibiotic or anti-infective therapy is the mainstay for treating DFIs, but for more complex forms such as osteomyelitis (inflammation of the bone), surgical debridement may also be needed. Topical agents (such as silver preparations, antiseptics, bacteriophage therapy, honey dressings) have been used (typically off-label) in many cases but these are typically adjunctive to the systemic treatments and not necessarily used as standalone therapy, except for potentially very mild and/or superficial cases.

Currently available topical drugs have limited efficacy for treating DFIs

While a standalone topical therapeutic option would be convenient for patients (given the relative ease of drug administration), aid in treatment compliance (particularly in patients intolerant to oral drugs), provide a concentrated dose at the presumed site of interest and also reduce the risk of systemic side effects associated with oral or intravenous antibiotics, recent treatment guidelines by the International Working Group on the Diabetic Foot (IWGDF) and the Infectious Diseases Society of America (IDSA) highlight the effectiveness limitations of currently available and/or approved topical therapies or antibiotics. As discussed below, we believe that topical R327 has the potential to deliver stronger clinical outcomes and efficacy.

While the IWGDF/IDSA guidelines recognise the theoretical advantages of topical antimicrobial therapy, the authors believe that, on balance, the published studies to date, which they believe may be characterised by a potentially high risk of bias in some cases, demonstrate 'inconsistency, imprecision, and low certainty' and thus do not demonstrate a significant clinical benefit of currently available topical antibiotics for the treatment of diabetes-related soft tissue or bone infections. They also report that there is insufficient evidence as to whether adjunctive application of topical agents would materially affect clinical outcomes. Other sources have also commented that there is limited

high-quality evidence on the appropriate indications, dosages and pharmacokinetics for currently available topical anti-infectives for treating mild DFIs.

R327's mechanisms highlighted in WHO report

R327 is designed to provide a multi-faceted mechanism of action, described in our initiation note, whereby the synthetic anti-infective drug candidate is expected to work on multiple levels by interrupting bacterial energy production (which normally involves the production of adenosine triphosphate, ATP), 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 World Health Organization (WHO) added R327 to its 2023 report on antibacterial agents in clinical development and preclinical development. Notably, R327 has been defined by the WHO as an ATP production disruptor and is the only listed compound under this category in the report. This confirms the unique mechanistic nature of R327 (compared to other anti-infectives under development) and could support market differentiation (as well as the effectiveness shown to date against drug-resistant bacteria) provided eventual regulatory approval.

R327 seeking DFI breakthrough

Owing to its broad anti-infective capability, Recce believes that topical R327 can be effective in treating mild DFIs (as more advanced cases, which penetrate into deeper tissues, may still require systemic therapy). 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.

Promising initial R327 DFI data in Australian study

Recce announced in January 2024 that interim data from its Phase I/II study assessing topical R327 in DFIs met all primary endpoints on five patients, providing 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. In February Recce reported that the study's independent safety committee (ISC) confirmed that the study is achieving its primary safety, tolerability and efficacy endpoints (including resolving or curing bacterial DFIs).

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

Patient	Application frequency	Age (years)/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, in our view. Following this interim data, the study's ISC and the company both agreed to expand the DFI study and broaden study inclusion criteria. In Recce's April business update, the company confirmed its intent to expand its DFI programme domestically and internationally, and it highlighted that it has identified several study sites, including a Victoria-based regional health services centre described as one of the largest of its kind in Australia and a Western Australia-based private hospital, which it expects to activate in Q2 CY24.

Topical R327 DFI programme advancing to Indonesian Phase III

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

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

As stated previously, we do not believe that the Phase III Indonesian study would be sufficient on its own to support registration applications in the US or Europe, but we note that Recce is planning to file a US IND for the topical R327 formulation in Q4 CY24, which would permit the initiation of a US study of the topical formulation.

Topical R327 program expanding to additional skin indications

In June 2024, Recce reported that it received Human Research Ethics Committee approval in Australia to start a centralised open-label Phase II study assessing R327 as a topical, broad-spectrum gel applied to acute bacterial skin and skin structure infections (ABSSSI), which comprise a broader range of conditions than the DFIs and burn wound infections assessed in prior topical R327 human trials. The study is primarily being conducted by Barwon Health, one of the Australia's largest comprehensive regional health services centres, which Recce believes will enable the trial to access a diverse patient population. The study is designed to assess the R327 gel's effectiveness and safety in treating a broad range of ABSSI indications, which, in addition to DFIs and burn wound infections, can also include necrotising fasciitis, post-operative wound infections, simple abscesses, boils, cellulitis and others.

The first patients are expected to be dosed in Q3 CY24 and we expect the company will provide updates on this study in CY25 and we note that the global ABSSSI market was valued by Fortune Business Insights at US$7.3bn in 2018 and was projected to reach US$25.9bn in 2032. We also highlight that drug-resistant bacterial strains, particularly methicillin-resistant Staphylococcus aureus (MRSA), remains a pressing concern with many skin and skin structure infections.

For the time being, for our modelling and valuation purposes, we continue to only include topical R327's potential for DFIs and burn wound indications. Once clinical data is generated in additional topical bacterial skin infection indications, we may revisit our assumptions to include additional ABSSSI indications in our forecasts.

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

Reiterating expectations for R327 DFI commercial potential

We continue to estimate that the annual US incidence of mild DFIs that can be potentially treated with a topical product would be approximately 150,000 a year and, at peak, topical R327 could potentially be used in about 25% of such cases. As we believe the morbidity risk in this indication (mild DFI) is lower than the lead cUTI or sepsis indications sought by IV R327 and we continue to assume an average net per-course pricing of approximately US$1,500 at US launch (versus our higher and unchanged assumed pricing of US$5,500 per treatment course for the IV indications described above), this results in estimated peak combined sales across both the US and Europe of US$102m in 2033.

As mentioned above, we expect earlier commercialisation in Indonesia and other ASEAN countries, potentially starting in H2 CY26. We assume that the prevalence of diabetes in ASEAN countries is c 47m, with 3% obtaining diabetic foot ulcers in a given year, and of these, 55% will be infectious and c 25% of such infections can be treated with topical IV R327, leading to a potential addressable market of c 195,000 cases per year in the region. At 20% assumed peak market share in the region, this would translate into c A$50m in peak sales, with Recce entitled to a 25% royalty according to our forecasts.

Phase I/II IV R327 rapid infusion study successfully completed

We continue to view the IV formulation as Recce's strongest commercial R327 opportunity, specifically the sepsis (and/or urosepsis) and cUTI indications under assessment. The company, in June 2024, reported it has completed the Phase I/II study (trial ID ACTRN12623000448640 at anzctr.org.au) assessing the safety, tolerability and pharmacokinetics (PK) of IV R327 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 the primary care and acute patient care settings. The company reported that the Phase I/II rapid infusion study met all its primary endpoints and demonstrated significant antibacterial activity.

The Phase I/II study was an open-label, adaptive design evaluation of the safety, PK and pharmacodynamics of various R327 IV dose levels (2,500mg to 4,000mg) and infusion rates (15 to 45 minutes) across 25 healthy subjects aged 18–65. Primary trial outcomes were relating to safety and tolerability, and these outcomes were favourable across all dose cohorts. No serious adverse events were reported and no clinically significant changes in relevant biomarkers were observed, supporting the safety profile of R327.

Exhibit 2: Phase I/II IV R327 Rapid infusion study cohort characteristics

Cohort	Dose	Number of subjects
1	2,500mg; 45-min infusion rate	9
2	3,000mg; 30min infusion rate	4
3	3,000mg; 15-min infusion rate	2
4	3,000mg; 20-min infusion rate	4
5	4,000mg; 20-min infusion rate	6

Source: Recce Pharmaceuticals

Secondary trial outcomes focussed on assessing R327 urine concentrations at various doses and infusions rates. Recce took urine samples from the patients dosed with IV R327 throughout the study and found that R327 was present in these samples and, more notably, that these urine samples demonstrated ex-vivo anti-infective properties, suggesting that the rapid infusion of R327 leads to urine concentrations capable of blocking bacterial growth in urine (which would be relevant to the UTI/urosepsis patient population). The company highlighted that most participants demonstrated significant R327 activity in their urine samples, notably in the first hour after the dose. For the most recent and highest-dose cohort (4,000mg and at a 20-minute infusion rate; n=6), where 10 urine samples were taken per participant over a six-hour period, samples from all of the participants demonstrated a marked reduction in *Escherichia coli (E. Coli)* bacterial growth over time (after *E.Coli* was introduced into each urine sample). Peak antimicrobial efficacy was achieved two-to-four hours post-infusion.

Based on the data from the dose-escalation phase in healthy volunteers of the above trial, Recce now plans to start a Phase II study of IV R327 in patients with cUTIs (including urosepsis patients), with initial patient recruitment and dosing guided for H2 CY24. We expect this study to be focused on test sites in Australia and New Zealand. The company plans to recruit 30 patients for the study and we will await further information from management, in terms of timelines and relevant endpoints for this study.

US IND filing guided for H2 CY24

Recce also expects to submit an IND application to the US FDA in H2 CY24, which would be directed towards a separate multiple-dose global (and US test site-centric) Phase II efficacy study in UTIs/urosepsis. The company's new guidance for funds-on-hand following the July/August 2024 financing (discussed below) is sufficient to maintain operations into FY26 (the period starting July 2025), including covering costs for the recently announced IV R327 Phase II study in cUTI/urosepsis patients discussed above. We now expect that Recce will likely only start materially recruiting subjects for this separate US-centric Phase II study towards Q2 CY25 or early Q3 CY25 (vs Q4 CY24 assumed previously), as we anticipate trial costs for US test sites to be significantly higher than those borne in Australia.

We assume this US-centric study will recruit c 40 to 80 patients with cUTIs and will be completed in Q1 CY26 (vs H2 CY25 previously). While this US-centric trial will technically be termed a Phase II study, we understand it will be designed to serve as one of the two studies necessary to meet a US New Drug Application (NDA). We assume that if the results of this urosepsis study are positive, a larger pivotal Phase III study would then begin and it could serve as the final study required for US registration. We anticipate that this Phase III study would be designed to assess both patients with cUTIs, as well as patients with sepsis (both urosepsis as well as other forms of sepsis).

While we have pushed back our anticipated start (and expected data readout) timelines for the US-centric Phase II trial, we currently maintain our projection for potential approval and commercialisation of IV R327 in sepsis and cUTI in H2 CY28. However, we may revisit our

assumptions once the US IND has been cleared by the FDA and/or greater clarity is provided by management on the expected data points and timelines for the US-centric study.

Recce to raise upto A$10m and extend runway to FY26

On 2 July 2024, Recce announced that it is raising A$10m in equity fundraising through an institutional placement (backed by binding commitments by participating investors including a A$2m commitment by NorthStar Impact Fund) of A$8m, priced at A$0.45/share (a 25% discount to the 28 June closing price of A$0.60/share), and an A$2.0m SPP that is being offered to remaining existing shareholders to allow them to also purchase a proportionate amount of shares also at A$0.45/share. The placement has now completed and settled, with the 17.8m new shares now listed for trading. The allotment of new shares under the SPP and their commencement of trading (and listing) is expected in the week of 5-9 August.

The majority ($7.5m) of the proceeds from the fundraising are going to be allocated towards clinical trials, including the Australia-focussed Phase II IV R327 UTI/Urosepsis trial described above, the planned domestic Phase II study for the topical R327 in ABSSSI indications, and the Phase III IV R327 study for DFI in Indonesia and ASEAN territories. Recce also has allocated A$1.5m for activities and costs relating to enabling the IND filing with the FDA for R327. A$1.0m is also allocated towards general working capital and other operating costs.

Following the offer, which we expect to be completed in full, Recce would have a pro-forma (31 March) gross cash position of A$18.5m (given that it had $8.5m in gross cash at 31 March). Further, the company expects to receive US$2.0m in grant funding from the US Department of Defense (DoD) in early FY25 (as discussed in our prior note) and it also anticipates receiving c A$5.4m in R&D funding advances in Q3 FY25 (Q1 CY25). The company expects these funding sources will enable the company to maintain its operations and fund its R&D programs into early FY26 (or H2 CY25).

Financials and valuation

Our local-currency denominated revenue forecasts are essentially unchanged (please see our prior note for details), although we have updated or forecasts and valuation to reflect the recent forex changes (we now assume US$0.67/A$, versus our prior assumption of US$0.65/A$). As a reminder, in Recce's quarterly cash flow (4C statement) update (for the period ending 31 March), it reported a net operating cash burn rate of A$4.7m and finished the quarter with A$8.5m in cash and equivalents. We estimate that the company's gross debt at quarter-end (31 March) was A$11.5m and we calculate the Q324e net debt at A$3.0m. We assume full completion of the A$10m share placement and SPP, and we now calculate a pro forma net cash position of A$7.0m (on 31 March).

We have made very minor changes to our FY24 estimates as we assume the US DoD grant will be received in FY25 (vs Q4 FY24 previously) and we have slightly trimmed our R&D expense forecast. We forecast FY24 net R&D expense and operating losses of A$14.6m and A$16.7m, respectively, versus our prior estimates of A$15.4m and A$14.2m, respectively.

For FY25, given Recce's latest guidance and our new assumption that the company will, at most, have very minor US-based clinical trial study site activities in FY25 (for both IV R327 and the topical R327), we have significantly reduced our FY25 R&D expenditure projections for both IV R327 (in sepsis and cUTI indications) and for topical R327 (for DFI and burn wound indications). We assume clinical study costs for US sites would be materially higher than similar costs for Australian and/or ASEAN study sites. We expect US clinical trial activities, when they start in H2 FY25, will focus on the US-centric multiple dose IV R327 Phase II study in UTIs and urosepsis. Our FY25 net R&D expenditure forecast and net operating cash burn estimates are now A$14.9m and A$14.0m, respectively, sharply lower than our prior estimates of A$51.2m and A$58.0m, respectively.

We expect Recce's R&D expense trends and its burn rate to rise substantially in FY26 as we model that the company will be engaging in more resource-intensive US clinical trials for the IV 327 and topical R327 programmes. We currently model a FY26 net operating burn rate of A$77.1m, driven by A$66.4m in projected net R&D costs.

The forex changes described above have a minor negative influence in our rNPV valuation, due to translation-related effects on projected future US revenue, but this is more than offset by the rolling forward of our estimates and the reduction in our FY25 R&D expense forecasts described above. We now obtain an rNPV valuation, inclusive of A$7.0m Q324e pro forma net cash, of A$688.5m (or A$3.07 per share), versus A$661.3m (or A$3.27 per share) previously. The reduced value per share is due to the anticipated increase in shares outstanding (from 204.0m prior to the placement and SPP to 226.2m after the completion of both) following the A$10m financing.

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	3,492	4,291	15%	619	2.74
R327 (IV)	Complicated UTI	H2 CY28	408	502	15%	69	0.31
R327 (topical)	Burn wounds	CY28	267	286	20%	51	0.23
R327 (topical)	Diabetic foot infections (ex-ASEAN)	CY29	124	135	15%	16	0.07
R327 (topical)	Diabetic foot infections (ASEAN)	H2 CY26	51	27	25%	7	0.03
Corporate costs				(73.5)		(73.5)	-0.33
Pro-forma Net cash (debt) at 31 Mar 2024 (assuming completion of Q3 CY24 A$10m equity financing)				7.0		7.0	0.03
Total equity value						688.5	3.07

Source: Edison Investment Research

While we assume the completion of the A$10m share placement and SPP will proceed in full and will fund Recce's operations into FY26, for modelling purposes, we anticipate that the company will raise an additional A$20m in late FY25 (vs A$60m previously), modelled as illustrative debt. We assume clinical trial-related costs for each of the four sought indications in our model (sepsis, UTIs, DFIs and burn wounds) will ramp up significantly in FY26. Any delays to the start of such activities would reduce our funding estimates over this period but may push back our potential launch forecasts.

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

We view sepsis as the primary driver of the company's valuation and expect Recce will prioritise the sepsis (and/or urosepsis) and cUTI indications. Assuming the company continues to develop all four planned clinical-stage indications and completes the A$10m share placement and SPP, we project Recce would need to raise an additional A$140m in total net proceeds by FY29 before becoming sustainably cash flow positive. Prior to the A$10m financing announcement and FY25 guidance, we had assumed a A$200m total financing requirement. In line with our modelling revisions described above, our new total funding projections assume that a greater proportion of the

future clinical trial-related activities (and patient subjects recruited in such studies) required to obtain regulatory approval (in the US and Europe) in key indications (such as cUTIs, sepsis and DFIs) will come from lower-cost sites in Australia (vs the US). As per the usual Edison methodology, we model these raises as illustrative debt. If our projected funding need of A$140m is raised through equity issuances at the prevailing market price of c A$0.46, our effective value per share would decrease to A$1.56 (including cash raised via equity).

Exhibit 4: Financial summary

A$(000)	2021	2022	2023	2024e	2025e	2026e
30-June	IFRS	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS						
Revenue	1,857	3,085	4,311	5,771	9,614	6,493
Cost of Sales	0	0	(0)	(0)	(0)	(0)
Gross Profit	1,857	3,085	4,311	5,771	9,614	6,493
Sales, General & Administrative	(9,511)	(7,677)	(9,779)	(7,564)	(7,449)	(8,098)
Net Research & Development	(5,657)	(6,285)	(7,330)	(14,552)	(14,925)	(66,418)
EBITDA	(13,311)	(10,878)	(12,797)	(16,345)	(12,761)	(68,023)
Depreciation, amortisation & other	(296)	(188)	(217)	(380)	(328)	(208)
Normalised Operating Profit (ex. amort, SBC, except.)	(8,389)	(10,809)	(12,689)	(16,725)	(13,089)	(68,231)
Operating profit before exceptionals	(13,607)	(11,065)	(13,014)	(16,725)	(13,089)	(68,231)
Exceptionals including asset impairment	0	0	54	0	0	0
Other	0	0	0	0	0	0
Reported Operating Profit	(13,607)	(11,065)	(12,960)	(16,725)	(13,089)	(68,231)
Net Finance income (costs)	94	79	(117)	(437)	(1,278)	(9,027)
Profit Before Tax (norm)	(13,513)	(10,986)	(13,131)	(17,162)	(14,367)	(77,258)
Profit Before Tax (FRS 3)	(13,513)	(10,986)	(13,077)	(17,162)	(14,367)	(77,258)
Tax	0	0	0	0	0	0
Profit After Tax and minority interests (norm)	(13,513)	(10,986)	(13,131)	(17,162)	(14,367)	(77,258)
Profit After Tax and minority interests (FRS 3)	(13,513)	(10,986)	(13,077)	(17,162)	(14,367)	(77,258)
Average Basic Number of Shares Outstanding (m)	155.4	174.1	174.0	191.1	215.1	226.2
EPS - normalised (A$)	(0.09)	(0.06)	(0.08)	(0.09)	(0.07)	(0.34)
EPS - normalised and fully diluted (A$)	(0.09)	(0.06)	(0.08)	(0.09)	(0.07)	(0.34)
EPS - (IFRS) (A$)	(0.09)	(0.06)	(0.08)	(0.09)	(0.07)	(0.34)
Dividend per share (A$)	0.0	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET						
Fixed Assets	501	439	608	537	341	277
Intangible Assets	0	0	0	82	82	82
Tangible Assets	501	439	608	455	259	195
Investments in long-term financial assets	0	0	0	0	0	0
Current Assets	21,181	12,185	1,947	6,335	21,714	24,519
Short-term investments	0	0	0	0	0	0
Cash	20,873	11,582	1,562	5,499	20,878	23,684
Other	308	603	386	836	836	836
Current Liabilities	(1,078)	(2,447)	(4,850)	(4,648)	(4,648)	(4,648)
Creditors	(1,078)	(2,447)	(1,802)	(2,414)	(2,414)	(2,414)
Short term borrowings	0	0	(3,048)	(2,234)	(2,234)	(2,234)
Long Term Liabilities	(100)	(115)	(295)	(11,390)	(31,390)	(111,390)
Long term borrowings	0	0	0	(11,099)	(31,099)	(111,099)
Other long term liabilities	(100)	(115)	(295)	(291)	(291)	(291)
Net Assets	20,504	10,061	(2,589)	(9,166)	(13,983)	(91,241)
CASH FLOW STATEMENT						
Operating Income	(13,607)	(11,065)	(12,960)	(16,725)	(13,089)	(68,231)
Movements in working capital	144	1,532	(152)	751	0	0
Net interest and financing income (expense)	94	79	(117)	(437)	(1,278)	(9,027)
Depreciation & other	296	188	217	380	328	208
Taxes and other adjustments	5,218	256	325	(0)	0	0
Net Cash Flows from Operations	(7,856)	(9,010)	(12,687)	(16,031)	(14,039)	(77,050)
Capex and capitalised expenditures	(76)	(40)	(39)	(119)	(131)	(144)
Acquisitions/disposals	0	0	0	(116)	0	0
Interest received & other investing activities	0	0	0	0	0	0
Net Cash flows from Investing activities	(76)	(40)	(39)	(235)	(131)	(144)
Net proceeds from share issuances	26,338	287	102	10,585	9,550	0
Net movements in long-term debt	0	0	0	9,618	20,000	80,000
Dividends	0	0	0	0	0	0
Other financing activities	(215)	(528)	2,604	0	0	0
Net Cash flows from financing activities	26,123	(240)	2,706	20,203	29,550	80,000
Effects of FX on Cash & equivalents	0	0	0	0	0	0
Net Increase (Decrease) in Cash & equivalents	18,191	(9,291)	(10,020)	3,937	15,379	2,805
Cash & equivalents at beginning of period	2,682	20,873	11,582	1,562	5,499	20,878
Cash & equivalents at end of period	20,873	11,582	1,562	5,499	20,878	23,684
Closing net debt/(cash)	(20,873)	(11,582)	1,487	7,833	2,675	3,719
Lease debt	127	75	251	199	199	199
Closing net debt/(cash) inclusive of IFRS16 lease debt	(20,746)	(11,507)	1,737	8,032	2,874	3,918
Free cash flow	(7,932)	(9,051)	(12,726)	(16,266)	(14,171)	(77,195)

Source: Company accounts, Edison Investment Research

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