

10 February 2026

All Eyes on Indonesian Phase 3 Trial

NEED TO KNOW

- Indonesian Phase 3 DFI trial readout approaching
- DoD contract signed for further burn wound collaboration
- 2QFY26 results and funding update

Indonesian Phase 3 DFI trial: Recce's registrational Phase 3 DFI trial of R327G in Indonesia continues to enrol and dose patients, with an interim analysis planned once 155 patients have been treated. Topline results are anticipated in 1QCY26, targeting a high-burden diabetes population. As such, this program remains the most significant near-term catalyst on the horizon, given its potential to validate R327G's clinical and commercial prospects,

US Department of Defense agreement for further cooperation in burn wounds: Recce's second US Army Cooperative Research and Development Agreement (CRADA) will evaluate RECCE 327 Gel (R327G) in a validated burn wound model, with preclinical data informing future military-focused development pathways.

2QFY26 results – funded for 8.7 quarters at current rate: In 2FQY26, Recce reported A\$0.4m cash on hand, quarterly operating cash outflows of A\$2.6m (including A\$2.1m R&D spend), and access to approximately A\$22.3m in total funding, combining cash and ~A\$21.8m of undrawn debt and equity facilities, including a loan facility from Avenue Venture Opportunity Fund II L.P., to support its advancing Phase 3 DFI trial and broader anti-infective pipeline.

Investment Thesis

Developing an entirely new class of anti-infectives for hard-to-treat infections: Recce is advancing a first-in-class platform based on acrolein-derived polymer technology. This synthetic approach offers a fundamentally different mechanism of action, designed to overcome multi-drug resistance and provide therapeutic options against some of the most challenging bacterial pathogens.

Novel mechanism of action: R327 exhibits a novel mechanism of action and is uniquely recognised by the WHO as the only anti-infective that disrupts ATP production. Notably, it remains water-soluble across all pH levels, including those of the human stomach, which supports its stability and broad therapeutic potential.

Substantial promise in preclinical testing: R327 is a novel, broad-spectrum anti-infective designed to overcome antimicrobial resistance, including superbug forms, even after repeated use, and has shown significant selective interaction with a broad range of bacterial cells and viruses in preclinical testing to date.

Valuation/Risks

We maintain our valuation of Recce at A\$764m, or A\$2.40 per share pending the release of detailed interim results. As such, this valuation uses a cash on hand of A\$3.2m as at end of 1QFY26, vs 2QFY26 cash of A\$0.4m, and does not factor in the R&D tax rebate of A\$5.3m received in 3QFY26. Key risks include clinical, regulatory, competitive, and financial risks.

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Recce Pharmaceuticals is a clinical-stage biopharmaceutical company which is developing and commercialising a new class of synthetic anti-infectives to address antibiotic-resistant bacteria (superbugs) and emerging viral pathogens. Patented lead candidate RECCE® 327 (R327) is being developed in a variety of formulations to treat potentially life-threatening infections including sepsis due to Gram-positive and Gram-negative bacteria including superbug forms. R327 is on the Pew Charitable Trust's Global New Antibiotics in Development Pipeline as the only synthetic polymer and sepsis drug candidate in development. www.recce.com.au

Valuation	A\$2.40 (unchanged)
Current price	A\$0.58
Market cap	A\$168m
Cash on hand	A\$0.4m (31 Dec 2025)

Upcoming Catalysts / Next News

Period	
1QCY26	Interim result – Ph 3 R327G: Indon.
1QCY26	R327G Ph 3 trial (ABSSSI) start
1HCY26	Filing IND for R327G
1HCY26	R327 Ph 2 trial UTI/urosepsis start
Mid-CY26	Potential launch of R327G: Indonesia

Share Price (A\$)



Source: FactSet, MST Access.

Year end 30 June, AUD unless otherwise noted

MARKET DATA

Price	\$	0.58
52 week high / low	\$	0.28-0.71
Valuation	\$	2.40
Market capitalisation	\$m	167.7
Shares on issue (basic)	m	289.2
Options / rights	m	32.9
Other equity	m	0.0
Shares on issue (diluted)	m	322.1

INVESTMENT FUNDAMENTALS		FY24A	FY25A	FY26E	FY27E	FY28E
Reported NPAT	\$m	(17.7)	(21.4)	(16.6)	(13.1)	(9.4)
Underlying NPAT	\$m	(17.7)	(21.4)	(16.6)	(13.1)	(9.4)
Reported EPS (diluted)	¢	(10.0)	(9.0)	(5.7)	(4.4)	(3.1)
EPS Underlying (diluted)	¢	(10.0)	(9.0)	(5.7)	(4.4)	(3.1)
Growth	%					
Underlying PER	x	nm	nm	nm	nm	nm
Operating cash flow per share	¢	-5.6	-7.1	-5.5	-4.2	-2.9
Free cash flow per share	¢	-5.7	-7.2	-5.5	-4.2	-2.9
Price to free cash flow per share	x	nm	nm	nm	nm	nm
FCF Yield	%	nm	nm	nm	nm	nm
Dividend	¢	0.0	0.0	0.0	0.0	0.0
Payout	%	0.0%	0.0%	0.0%	0.0%	0.0%
Yield	%	0.0%	0.0%	0.0%	0.0%	0.0%
Franking	%	0.0%	0.0%	0.0%	0.0%	0.0%
Enterprise value	\$m	164.1	160.2	166.8	169.9	169.3
EV/EBITDA	x	(9.2)	(7.5)	(10.2)	(13.2)	(24.9)
EV/EBIT	x	(9.2)	(7.4)	(10.2)	(13.2)	(24.7)
Price to book (NAV)	x	(14.1)	(54.8)	(18.0)	(14.0)	(15.2)
Price to NTA	x	(14.1)	(54.8)	(18.0)	(14.0)	(15.2)

KEY RATIOS		FY24A	FY25A	FY26E	FY27E	FY28E
EBITDA margin	%	nm	nm	nm	nm	nm
EBIT margin	%	nm	nm	nm	nm	nm
NPAT margin	%	nm	nm	nm	nm	nm
ROE	%	nm	nm	nm	nm	nm
ROA	%	nm	nm	nm	nm	nm
Net tangible assets per share	\$	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)
Book value per share	\$	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)
Net debt/(cash)	\$m	(3.6)	(7.5)	(0.9)	2.2	1.6
Interest cover/ (EBIT/net interest)	x	nm	nm	nm	nm	nm
Gearing (net debt/EBITDA)	x	nm	nm	nm	(0.2)	(0.2)
Leverage (net debt/(net debt + equity))	x	nm	nm	nm	(0.2)	(0.2)

DUPONT ANALYSIS		FY24A	FY25A	FY26E	FY27E	FY28E
Net Profit Margin	%	nm	nm	nm	nm	nm
Asset Turnover	x	nm	nm	nm	nm	nm
Return on Assets	%	nm	nm	nm	nm	nm
Leverage	x	nm	nm	nm	nm	nm
Return on Equity	%	nm	nm	nm	nm	nm

Clinical development pipeline

Anti-bacterial programs	Indication	Status
R327 (intravenous)	Sepsis associated with QIDP targets	Phase 2 ready
R327 (intravenous)	UTI/Urosepsis	Phase 2 ready
R327 (topical)	Burn wound infection	Phase 1b/2a completed
R327 (topical)	Burn wound infection (gel wound dressing)	In development with DoD
R327 (topical)	Diabetic foot infections (Indonesia)	Phase 3 underway
R327 (topical)	ABSSSI/DFI (Australia)	Phase 2 completed
R327 (topical)	ABSSSI (Australia)	Phase 3 ready
R327 (inhalation)	Hospital/Ventilator Acquired Pneumonia (HAP/VAP)	Preclinical
R435 (oral)	Helicobacter pylori in stomach ulcers	Preclinical
Anti-viral programs	Indication	Status
R327 (nasal)	SARS-CoV-2 & other viral infections	Preclinical
R529	Viral infections	Preclinical

HALF YEARLY DATA		2H23	1H24	2H24	1H25	2H25
Total Revenue	\$m	4.3	2.4	2.7	6.9	0.7
Operating expenses	\$m	(8.2)	(9.6)	(13.2)	(14.7)	(14.4)
EBITDA	\$m	(3.9)	(7.2)	(10.6)	(7.7)	(13.7)
EBIT	\$m	(3.9)	(7.2)	(10.6)	(7.8)	(13.7)
PBT	\$m	(3.9)	(7.2)	(10.5)	(7.7)	(13.7)
Reported NPAT	\$m	(3.9)	(7.2)	(10.5)	(7.7)	(13.7)

Source: Company reports, MST Access estimates

12-MONTH SHARE PRICE PERFORMANCE (A\$)



PROFIT AND LOSS		FY24A	FY25A	FY26E	FY27E	FY28E
Revenue	\$m	0.0	0.0	0.0	1.3	6.3
Other income	\$m	5.0	7.6	7.3	7.3	7.3
Total Revenue	\$m	5.0	7.6	7.3	8.6	13.6
Operating expenses	\$m	(22.8)	(29.1)	(23.6)	(21.4)	(20.4)
EBITDA	\$m	(17.8)	(21.5)	(16.3)	(12.8)	(6.8)
Depreciation & Amortisation	\$m	(0.1)	(0.1)	(0.1)	(0.0)	(0.0)
EBIT	\$m	(17.8)	(21.5)	(16.3)	(12.9)	(6.8)
Net interest	\$m	0.2	0.1	(0.2)	(0.3)	(2.6)
Pretax Profit	\$m	(17.7)	(21.4)	(16.6)	(13.1)	(9.4)
Tax expense	\$m	0.0	0.0	0.0	0.0	0.0
Reported NPAT	\$m	(17.7)	(21.4)	(16.6)	(13.1)	(9.4)
Underlying NPAT	\$m	(17.7)	(21.4)	(16.6)	(13.1)	(9.4)
End of year shares	m	231.9	288.4	299.2	309.2	319.2

GROWTH PROFILE		FY24A	FY25A	FY26E	FY27E	FY28E
Revenue	%	nm	nm	nm	nm	nm
EBITDA	%	nm	nm	nm	nm	nm
EBIT	%	nm	nm	nm	nm	nm
Reported NPAT	%	nm	nm	nm	nm	nm
DPS	%	nm	nm	nm	nm	nm

BALANCE SHEET		FY24A	FY25A	FY26E	FY27E	FY28E
Cash	\$m	4.4	10.4	3.9	0.8	1.3
Receivables	\$m	0.2	0.4	0.4	0.4	0.4
Inventory	\$m	0.0	0.0	0.0	0.0	0.0
Other	\$m	0.6	0.5	0.5	0.5	0.5
Current assets	\$m	5.1	11.4	4.8	1.7	2.3
PPE	\$m	0.4	0.4	0.4	0.3	0.3
Right-of-use assets	\$m	0.8	0.6	0.6	0.6	0.6
Intangible assets	\$m	0.0	0.0	0.0	0.0	0.0
Other	\$m	(0.0)	0.0	0.0	0.0	0.0
Non current assets	\$m	1.2	1.0	1.0	1.0	1.0
Total assets	\$m	6.4	12.4	5.8	2.7	3.2
Trade and other payables	\$m	14.4	3.0	3.0	3.0	3.0
Borrowing and leases	\$m	0.2	2.5	2.5	2.5	2.5
Other	\$m	0.5	0.6	0.6	0.6	0.6
Current liabilities	\$m	15.1	6.1	6.1	6.1	6.1
Borrowing and leases	\$m	0.6	0.4	0.4	0.4	0.4
Other liability	\$m	0.2	8.9	8.9	8.9	8.9
Non current liabilities	\$m	0.8	9.3	9.3	9.3	9.3
Total liabilities	\$m	15.9	15.5	15.5	15.5	15.5
Net assets	\$m	(9.5)	(3.1)	(9.6)	(12.8)	(12.2)
Share capital	\$m	54.8	81.5	91.5	101.5	111.5
Retained earnings	\$m	(70.1)	(91.5)	(108.1)	(121.2)	(130.7)
Other	\$m	5.7	7.0	7.0	7.0	7.0
Total equity	\$m	(9.5)	(3.1)	(9.6)	(12.8)	(12.2)

CASH FLOW		FY24A	FY25A	FY26E	FY27E	FY28E
Net loss for period	\$m	(17.7)	(21.4)	(16.6)	(13.1)	(9.4)
Depreciation & Amortization	\$m	0.1	0.1	0.1	0.0	0.0
Changes in working capital	\$m	4.3	(0.7)	0.0	0.0	0.0
Other	\$m	0.3	1.6	0.0	(0.0)	(0.0)
Operating cash flow	\$m	(13.0)	(20.4)	(16.5)	(13.1)	(9.4)
Payments for PPE	\$m	(0.1)	(0.0)	(0.0)	(0.0)	(0.0)
Other	\$m	0.0	(0.4)	0.0	0.0	0.0
Investing cash flow	\$m	(0.1)	(0.4)	(0.0)	(0.0)	(0.0)
Equity	\$m	10.5	26.6	10.0	10.0	10.0
Borrowing and Lease liability net payments	\$m	5.6	0.3	0.0	0.0	0.0
Other	\$m	(0.0)	(0.0)	0.0	0.0	0.0
Financing cash flow	\$m	16.0	26.9	10.0	10.0	10.0
Cash year end	\$m	4.4	10.4	3.9	0.8	1.3
Free cash flow	\$m	(13.2)	(20.9)	(16.6)	(13.1)	(9.4)

2QFY26 Update: Indonesian Phase 3 in Focus

Recce's 2QFY26 financial performance featured A\$0.4m cash on hand at quarter-end and operating cash outflows of A\$2.6m, comprising A\$2.1m in research and development spend, A\$0.5m in staff costs, and A\$0.7m in administration and corporate expenses, alongside A\$0.28m in related-party payments to executives and directors. The company also reported access to A\$22.3m of total available funding, combining cash with A\$21.8m of undrawn facilities, including a secured loan facility provided by Avenue Venture Opportunity Fund II L.P. and an at-the-market equity facility with Acuity Capital. Together, this represents an estimated 8.7 quarters of funding at the current operating cash burn rate.

Indonesian Phase 3 DFI trial

Recce is conducting a registrational Phase 3 trial of its topical RECCE 327 Gel (R327G) for diabetic foot infections (DFIs) in Indonesia, a market with more than 20.9 million adults living with diabetes and a substantial hospital cost burden per DFI patient. Dosing commenced in late September 2025, with patients now being enrolled and treated across multiple activated clinical sites.

The study plans to enrol up to 310 patients, randomised to receive either R327G or placebo, and is designed to support regulatory approval if the results are positive. The primary endpoint is clinical response assessed using the FDA-recognised Lipsky Scale, with secondary endpoints including an overall DFI wound score and safety and tolerability of R327G. An interim analysis is built into the BPOM-approved protocol at approximately 155 patients, which the company expects to be highly statistically significant on the current statistical plan, with interim topline data guided for 1QCY26 under Expedited Regulatory Review status. For investors, this interim readout is a key near-term catalyst, with potential to support Indonesian approval discussions, regional partnering across ASEAN and the Middle East, and broader commercial validation of R327G in a large, underserved DFI market.

US Government burn wound collaborations

Recce has expanded its US Government collaborations through a second Cooperative Research and Development Agreement (CRADA), this time with the US Army Institute of Surgical Research (USAISR), the Army's premier combat casualty and burn care research centre. Under this CRADA, USAISR will evaluate R327G in its validated Walker-Mason rat model of burn wound infection, a preclinical model specifically designed to mimic battlefield burn injuries and the ensuing systemic response.

The study will assess whether R327G can significantly reduce bacterial burden in infected burn wounds caused by methicillin-resistant *Staphylococcus aureus* (MRSA ATCC 43300) and *Pseudomonas aeruginosa* (ATCC 27853), two major, drug-resistant pathogens frequently isolated from burn patients and associated with high mortality. R327G, a topical formulation of Recce's lead broad-spectrum synthetic anti-infective R327, is being developed as an amorphous hydrogel wound dressing intended for frontline deployment in military field kits, as well as broader use in clinical and post-operative settings.

This second CRADA builds on Recce's existing agreement with the US Army Medical Research Institute of Infectious Diseases (USAMRIID) and a recent Congressionally Directed Medical Research Programs (CDMRP) grant, highlighting growing US Government interest in R327 across multiple operational and therapeutic applications. For investors, the USAISR collaboration offers non-dilutive validation in a high-need burn care segment and could lay the groundwork for future government-funded trials, procurement pathways, or strategic partnerships in both military and civilian burn wound markets.

Thesis: Near-Term Topical Opportunity with R327G

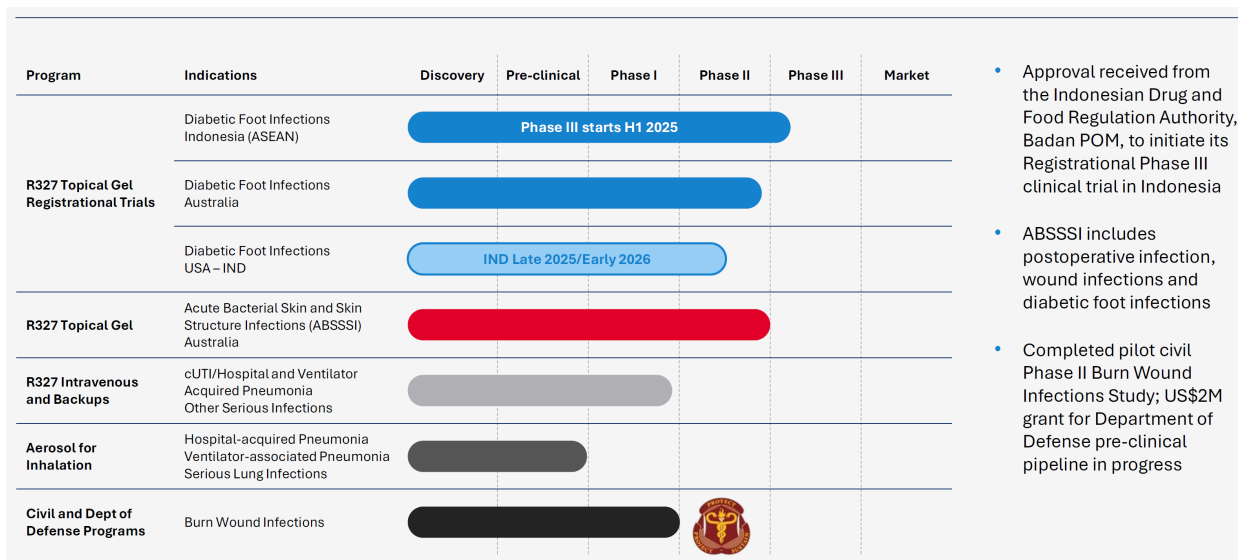
Recce's unique value proposition lies in its proprietary, patented compounds – RECCE® 327 (R327), RECCE® 435 (R435), and RECCE® 529 (R529) – which feature a novel, multi-layered mechanism of action that distinguishes them from traditional antibiotics.

These broad-spectrum polymer compounds are engineered to retain efficacy against resistant pathogens and have secured key regulatory designations, including FDA Fast Track status, FDA Qualified Infectious Disease Product (QIDP) designation, and World Health Organization recognition. Recce stands out among ASX-listed biotech companies focused on antimicrobial resistance with over 40 granted patents, non-dilutive government funding, and early clinical validation.

Recce's lead candidate, R327, is currently in multiple clinical trials targeting a wide range of drug-resistant bacterial infections, including urinary tract infections (UTIs), urosepsis, diabetic foot infections (DFIs), burn wounds, and acute bacterial skin and skin-structure infections (ABSSSIs). In-vitro studies have shown broad-spectrum activity against ESKAPE pathogens and consistent efficacy across 25 serial passages, with no observed resistance, unlike traditional antibiotics such as amoxicillin. A serial passage for antibiotics is a laboratory method where bacteria are repeatedly cultured in increasing concentrations of an antibiotic to study the development and evolution of antibiotic resistance.

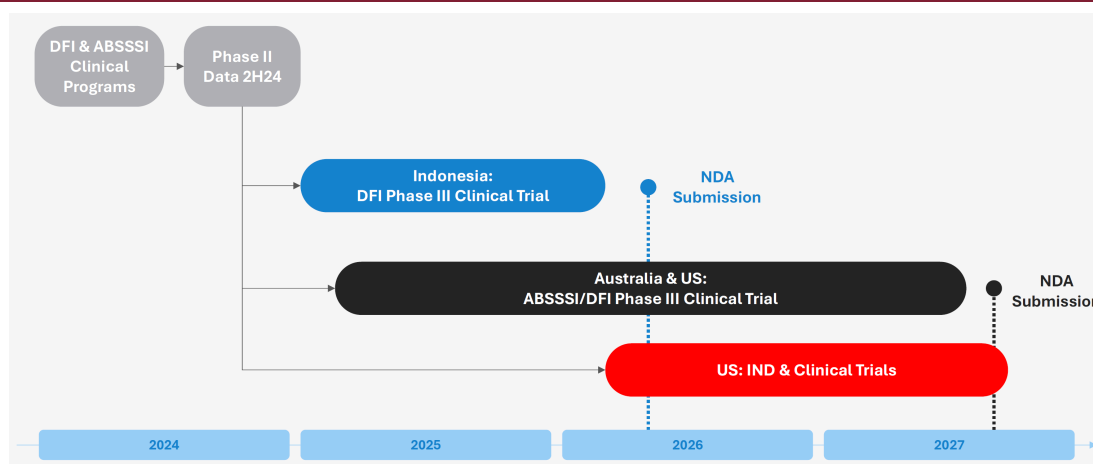
The company expects interim results for its registrational Phase 3 trial of R327G for DFIs in Indonesia by early CY2026. A separate Phase 3 trial for ABSSSIs in Australia is scheduled to start in 1QCY26.

Figure 1: Program pipeline for 2025



Source: Recce Pharmaceuticals.

Figure 2: Commercialisation pathway for R327G



Source: Recce Pharmaceuticals.

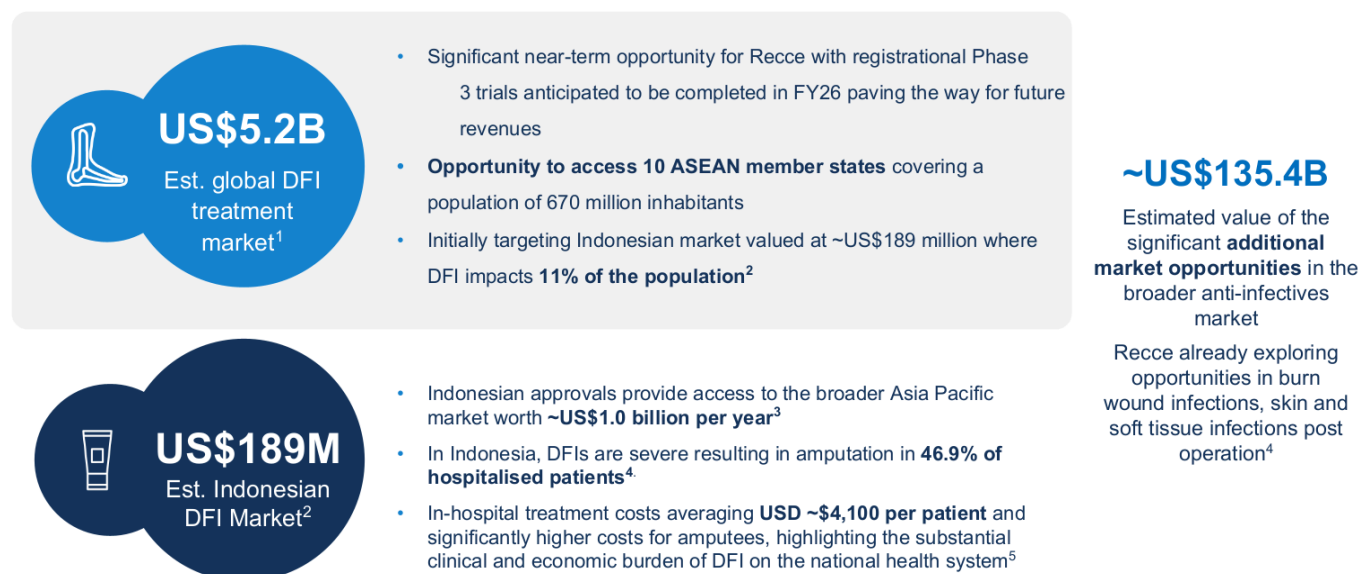
Financing activities and funding runway

- Recce has an At-the-Market (ATM) Subscription Agreement with Acuity Capital, offering standby equity capital. The ATM has been extended to 31 January 2031, with 4.5m shares held as collateral as at the 1QFY26 end.
- As at 31 December 2025, total financing facilities amounted to A\$30.6m, of which A\$11.5m was drawn. This included loan facilities entered into with Avenue Venture Opportunity Fund II L.P. (17 June 2025) and other equity-linked arrangements. These provide financial flexibility and enhance the company's capacity to meet funding requirements for its ongoing clinical and corporate plans over the near term.

Near-term catalysts

- Investors should watch for trial progress in Indonesia, updates on the planned Phase 3 study in Australia, and upcoming regulatory submissions, as these milestones will shape Recce's near-term growth prospects.
- The main near-term catalyst is the interim analysis from the pivotal Phase 3 clinical trial in Indonesia for DFIs, expected in 1QCY26. Interim results could influence regulatory and commercial planning and pathways.
- Successful interim data from the Indonesian trial may expedite local regulatory approvals under Indonesia's streamlined, fast-track drug approval environment. The new regulatory regime is designed to reduce approval timelines and encourage international clinical research collaboration, especially in high-need areas such as diabetes-related infections. A positive study could enable commercial launch in Indonesia by mid 2026, unlocking substantial value and potential for regional expansion. Over 11% of the adult population in Indonesia lives with diabetes, and the prevalence of DFIs and existing gaps in effective therapies provide a significant commercial opportunity for Recce should the trial succeed. Figure 3 highlights the company's opportunity in DFIs in Indonesia and ASEAN.

Figure 3: Overview of the opportunity in DFIs in ASEAN and Indonesia



Source: Recce Pharmaceuticals. Source: (1) Grand View Research, *Diabetic Foot Ulcer Treatment Market Size, 2023*. (2) *Diabetes Atlas, International Diabetic Federation and Prof EM Yunir, Faculty of Medicines, University of Indonesia*. (3) *Business Market Insights, Asia Pacific Diabetic Foot Ulcer Market, 2021*. (4) Grand View Research, *Anti-Infective Agents Market Size, 2023*. (5) <https://doi.org/10.1016/j.heliyon.2024.e41263>.

Valuation

We retain our risk-adjusted NPV-based valuation of Recce at A\$764m, or A\$2.40 per share, pending the release of detailed interim results. The valuation reflects a cash balance of A\$3.2m at 30 September 2025, versus \$0.4m at 31 December 2025, and dilution from an assumed 30m-share capital raising over the next 3 years. We have incorporated 32,919,423 options and performance rights outstanding, exercisable at various prices. As such, our fair value of the shares on a fully diluted basis is A\$2.17 per share. The breakdown of our rNPV model, which uses a 12.5% discount rate, is shown in Figure 4. Our valuation assumes a go-it-alone strategy with gross margins upon launch of 92%, with costs (R&D, launch and marketing) paid by Recce.

Figure 4: rNPV-based valuation for Recce Pharmaceuticals

Product	Status	Indications	Dose (delivery)	Launch	Peak sales (US\$m)	NPV*(US\$m)	Likelihood of approval	rNPV (A\$)
R327	Phase 1b/2a	Sepsis associated with QIDP targets (<i>E.coli</i> and <i>Staph aureus</i>)	Intravenous	2030	1704	2000	15%	454,497,091
R327	Phase 1b/2a	Complicated UTI (cUTI)	Intravenous	2030	219	126	19%	36,391,126
R327	Phase 1b/2a	Burn wounds (broad spectrum)	Topical	2027	292	192	20%	58,323,774
R327	Phase 3 (ready)	Acute Bacterial Skin and Skin Structure Infections (ABSSSI)	Topical	2026	402	386	20%	117,021,938
R327	Phase 3 (ready)	Diabetic foot infections (DFI) (ASEAN)	Topical	2026	109	62	30%	93,585,131
R327	Preclinical	Hospital/Ventilator Acquired Pneumonia (HAP/VAP)	Inhalation	2033	55	1	5%	1,831,455
R327	Preclinical	Bacterial sinusitis	Intravenous and intranasal	n/a				-
R435	Preclinical	<i>Helicobacter pylori</i> in stomach ulcers	Oral	n/a				-
R328	Preclinical	<i>Mycobacterium abscessus</i>	Intravenous	n/a				-
R327	Preclinical	COVID & Influenza	Intranasal	n/a				-
R529	Preclinical	COVID	Intravenous and intranasal	n/a				-
Cash position as at 30 September 2025 (A\$)								3,165,096
Shares outstanding (incorporating assumed 30m new shares issued for future capital raisings)								319,183,422
rNPV/share (A\$)								2.40

Source: MST Access estimates.

Near-term strategic priorities and capital requirements

In the near term, Recce's strategic focus is centred on advancing the topical formulation of R327 (R327G) for the treatment of ABSSSIs and DFIs. This prioritisation is driven by the potential for early commercialisation in these indications, supported by ongoing and upcoming pivotal Phase 3 studies in Indonesia and Australia. Nonetheless, our valuation assumes that Recce will simultaneously progress all of its clinical-stage indications in parallel. As such, we assume Recce will need to raise a further A\$105m to advance its IV programs (sepsis and urosepsis) through to commercial readiness. Notably, should the company choose to prioritise the development of R327G for ABSSSIs and DFIs – temporarily suspending other programs until after the initial commercial approval of R327G – the aggregate funding requirement would be reduced. In this scenario, Recce could leverage post-launch commercial revenues to support the subsequent resumption of research and development activities for the remaining targeted indications.

Figure 5: Timelines assumed in our valuation

Formulation		YE December	2025	2026	2027	2028	2029	2030	2031	2032	2033
IV	Sepsis associated with QIDP targets (<i>E.coli</i> and <i>Staph. Aureus</i>)				Phase 2	Phase 3	Phase 3	Launch			
IV	Complicated UTI			Phase 2	Phase 2	Phase 3	Phase 3	Launch			
Topical	Burn wound infections (Broad Spectrum)		Phase 2	Phase 2	Phase 3	Launch					
Topical	Acute Bacterial Skin and Skin Structure Infections (ABSSSI)		Phase 3	Launch							
Topical	Diabetic foot infections (DFI) - Indonesia (ASEAN)		Phase 3	Launch							
Topical	Diabetic foot infections (DFI) - USA			IND	Phase 2	Phase 3	Launch				
Inhalation	Hospital/Ventilator Acquired Pneumonia (HAP/VAP)			Preclinical		Phase 1	Phase 2	Phase 2	Phase 3	Phase 3	Launch

Source: MST Access forecasts.

Sensitivities and risks

Our valuation is sensitive to both clinical catalysts and associated risks. A positive interim readout in the Indonesian Phase 3 DFI trial could accelerate approval and increase the valuation. Likewise, strong Phase 3 results in Australia could expand markets and boost valuation. Early regulatory success would further strengthen investor confidence and upside potential.

Beyond technological risk, Recce is subject to various risks typically associated with biotech companies in the early stages of drug development, including the possibility of unfavourable outcomes in clinical trials, regulatory decisions, success of competitors, financing, and commercial risk.

Technology: Recce is a pioneer in developing a new class of anti-infectives based on acrolein polymer technology with a clinical strategy targeting major unmet medical needs and markets. Despite the relative lack of new anti-infective categories emerging over the past several decades, and the rise of antimicrobial resistance in the meantime, it remains to be seen whether Recce can prove efficacy in human clinical trials with its synthetic polymer approach.

Clinical trials: Technology aside, clinical risk remains significant given the early stage of clinical development and the task at hand. Developing a new antimicrobial treatment depends on multiple factors, including the vulnerability of the host, the virulence of the organism, and the use of antimicrobials that are both efficacious on repeated use and able to penetrate tissue in time to prevent unwanted spread. As a non-traditional synthetic compound, the acquisition of resistance to Recce products may prove harder for micro-organisms, but this is yet to be established in human trials. Variability in timelines of clinical trials related to speed of enrolment in the expanded Phase 2 trial and both Phase 3 trials also adds to the raft of clinical risks at this stage.

Funding risk: The company is currently funding all clinical programs and may need to raise additional capital to support studies of new clinical targets. Any shortfall in the amount raised or underestimation of forecasted costs may add to funding risk and the ability to raise capital in the future.

Regulatory: QIDP status is an FDA designation for antibacterial or antifungal drugs intended to treat serious or life-threatening infections, especially those caused by resistant or emerging pathogens, and provides sponsors with key benefits in terms of accelerating the regulatory process and enhancing market protection. Notwithstanding gaining QIDP status in sepsis, Recce will need to gain approval from the FDA or international regulatory bodies for marketing in the US or other global markets before entering a market, assuming clinical data is positive.

Commercialisation and reimbursement: In the absence of a development partner, and assuming clinical development is successful and regulatory approvals are achieved, the company will need to secure manufacturing at scale, quality control, marketing, and distribution of its products. Although manufacturing can be outsourced to a degree, maintaining the low cost of goods, Recce's strategy of maintaining all rights to the technology through to launch and beyond adds considerable risk to the choice of distributor and distribution strategy overall.

Intellectual property: We consider intellectual property risk as low, given the company's broad portfolio of patents in all key geographies. Nonetheless, given its go-it-alone commercialisation strategy, Recce may be forced to defend its intellectual property through litigation and, in the absence of a partner or licensor, absorb all legal costs.

Personal disclosures

Chris Kallos, CFA received assistance from the subject company or companies in preparing this research report. The company provided them with communication with senior management and information on the company and industry. As part of due diligence, they have independently and critically reviewed the assistance and information provided by the company to form the opinions expressed in this report. They have taken care to maintain honest and fair objectivity in writing this report and making the recommendation. Where MST Financial Services or its affiliates has been commissioned to prepare content and receives fees for its preparation, please note that NO part of the fee, compensation or employee remuneration paid has, or will, directly or indirectly impact the content provided in this report.

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Recce Pharmaceuticals (RCE.AX) | Price A\$0.58 | Valuation A\$2.40;

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