EDISON

Recce Pharmaceuticals

R327G progressing towards commercialisation

Commercial agreement and corporate update

Healthcare

4 November 2026

Recce recently announced an exclusive commercial agreement with Arrotex Pharmaceuticals for the marketing and distribution of the topical gel formulation (R327G) of lead anti-infective drug candidate RECCE 327 (R327) for the treatment of diabetic foot infections (DFIs) in Australia and New Zealand. This comes on the heels of blinded data from Recce's Phase III Indonesian DFI study showing encouraging safety and efficacy in DFIs, with unblinded data expected in the coming weeks. If positive, we anticipate that Recce will proceed with regulatory approval applications in Indonesia and other ASEAN nations, potentially marking Recce's transition to a commercial-stage company. We value Recce at A$658.4m, or A$2.15 per share.

Year end	Revenue (AUDm)	PBT (AUDm)	EPS (AUD)	DPS (AUD)	P/E (x)	Yield (%)
6/25	7.0	(22.1)	(0.09)	0.00	N/A	N/A
6/26	9.4	(15.4)	(0.05)	0.00	N/A	N/A
6/27e	6.8	(41.2)	(0.14)	0.00	N/A	N/A
6/28e	19.4	(60.4)	(0.20)	0.00	N/A	N/A

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

Australasian licensing deal boosts R327G's commercial trajectory

Recce's license and commercialisation agreement with Arrotex Pharmaceuticals covers the commercialisation of R327G in Australia and New Zealand, with Recce expected to capture a significant percentage of the gross margin. We believe the operational framework of the deal is very favourable as Arrotex provides the required and established regulatory, market access and commercialisation capabilities in the region, and, hence, Recce will not need to invest in a dedicated salesforce or in additional region-specific regulatory resources.

Promising blinded R327G Phase III DFI results

Recce on 20 October announced that a review of blinded study data from its ongoing Phase III registrational study of R327G for the treatment of DFIs indicates strong efficacy and an excellent safety and tolerability profile across the study. We believe this is highly encouraging as it suggests that the treatment arm (R327G) could be providing a therapeutic effect, as in our view it would be highly unusual for a placebo topical treatment arm to lead to the positive efficacy findings reported to date. Recce expects the study's data monitoring committee (DMC) to provide an unblinded analysis on c 75 patients in the coming weeks. Positive results could lead to regulatory approval submissions in Indonesia and ASEAN territories.

Valuation: Minor adjustments on Arrotex deal

Our valuation is based on a relative risked net present value (rNPV) calculation with a 12.5% cost of equity. We have rolled forward our estimates and included contributions from the Arrotex agreement. We now obtain an rNPV, including A $8.7m Q127 estimated net debt, of A$658.4m (or A$2.15 per share), versus A $657.3m (or A$2.19 per share) previously. The lower value per share is due to increased shares outstanding following the completion of the SPP.

Price	**AUD0.355**
Market cap	**AUD109m**
Estimated net cash/(debt) at 30 September 2026	AUD(8.7)m
Shares in issue	305.8m
Code	RCE
Primary exchange	ASX
Secondary exchange	FSE

Share price performance



%	1m	3m	12m
Abs	9.2	(6.6)	(11.3)
52-week high/low		AUD0.7	AUD0.3

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 diabetic foot infections, sepsis, acute bacterial skin and skin structure infections, burn wound infections and urinary tract infections.

Next events

Unblinded results from Indonesian Phase III R327G DFI study	Q4 CY26

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Edison profile page

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Licensing deal secured for Australia and New Zealand

As Recce continues to advance its separate Indonesian and Australian-based Phase III registrational studies for R327G in DFIs, the company announced an exclusive license and commercialisation agreement with Arrotex Pharmaceuticals, a subsidiary of DBG Health. Formed by the 2019 merger of Apotex Australia and Arrow Pharmaceuticals, Arrotex is believed to be Australia's largest and most diversified generic and private-label pharmaceuticals provider, offering a wide range of prescription drugs across multiple therapeutic areas.

Under the terms of their agreement, Arrotex obtains exclusive commercialisation rights for R327G for the treatment of DFIs in Australia and New Zealand, with Recce responsible for manufacturing and supply of product. Recce is to receive 'a significant profit share of gross margin from product sales'. While specific terms have not been disclosed, the operational framework of the deal is favourable for Recce as Arrotex provides the required and established regulatory market access and commercialisation capabilities in the covered territories, and, hence, Recce will not need to invest in a dedicated salesforce or in additional region-specific regulatory resources. Arrotex possess the required infrastructure and healthcare relationships needed to optimise R327G's sales potential. There are no upfront or milestone payments as part of the Arrotex-Recce R327G agreement.

While Arrotex's core business has been generic drugs and affordable private-label products, it is also involved in the marketing and distribution of innovative, differentiated and/or higher-value added treatments, such as Pfizer's Enbrel, CStone Pharmaceuticals' sugemalimab and Lenz Therapeutics' Vizz. We see R327G as falling within this proprietary and novel branded product category provided it receives regulatory approval, given its novel chemistry and mechanism of action (as an adenosine triphosphate, ATP, production disruptor) and its potential niche as the sole topical treatment approved for DFIs. One of the key competitive advantages for R327G in the treatment of DFIs is that, to our knowledge, no topical antibiotic has specific, globally recognised approval for usage in this indication.

Australian Phase III DFI study underway

As a reminder, Recce received approval in June 2026 to proceed with its Australian pivotal Phase III study of R327G in patients with DFIs, including patients with mild to moderate infections and infected ulcers below the knee. Recce expects the Phase III study to enrol 208 patients in total by the end of CY27, and an interim analysis by an independent DMC is planned once 50% of patients have completed treatment.

In the study, patients are being randomised between R327G and one of four physician-selected comparator antibiotics. The trial builds on positive results reported in February 2025 from the company's open-label Phase II Australian study for R327G in the treatment of acute bacterial skin and skin structure infections (ABSSSI), including patients with DFIs. This Phase II study achieved all primary and secondary efficacy endpoints and met plasma pharmacokinetics (PK) expectations. After seven days of treatment, 86% of patients (25 of 29) treated with R327G had a successful clinical response, and at 14 days of treatment, 93% (27 of 29) had achieved a primary efficacy endpoint. R327G was also reported to be safe and well tolerated, with no serious adverse events.

The Phase III Australian study is intended to generate comparative data for R327G versus existing established antibiotic therapeutic options used for the treatment of DFIs.

The company reports that it also continues to progress in its negotiations to form a definitive agreement under the non-binding Middle East and North Africa (MENA) term sheet signed with an undisclosed pharma partner covering the region. The finalisation of this term sheet, in our view, would represent a material external validation of Recce's R327G programme. The term sheet, as discussed in our prior note, calls for the formation of a 10-year exclusive agreement between Recce and the licensee for commercialisation in countries including the Kingdom of Saudi Arabia, Gulf Cooperation Council countries, as well as Egypt, Algeria and Morocco. The licensee is reported to have a multibillion-dollar market capitalisation and a distribution network serving more than 30 international markets.

Australian commercialisation expected in H2 CY28

We note that under the terms of their recently signed agreement, Arrotex is only required to apply for Therapeutic Goods Administration (TGA) approval (the regulatory authorisation process for Australia) once R327G is approved by either the US FDA, the European Medicines Agency or another regulatory authority recognised by the TGA as a comparable overseas regulator. Hence, we do not believe that Indonesian or ASEAN market approval alone would require Arrotex to seek R327G's approval with the TGA. We continue to model that, regardless of the Indonesian Phase III study outcome,

positive results from the ongoing Phase III Australian study will be necessary for commercial approval. We continue to model potential commercialisation in Australia (now through Arrotex) in H2 CY28.

For the Australian market, given an estimated prevalence of 2.1 million individuals with diabetes, we assume that approximately 47,000 individuals will experience a DFI episode each year and, among them, up to 50% would be eligible for a topical treatment such as R327G. We project sales of about A$18m by CY32 and that Recce would be entitled to 40% of resulting gross profit (assuming a 90% gross margin). In terms of overall contribution to our valuation, we continue to view the ASEAN opportunity as meaningfully larger given the much higher population and resulting prevalence of diabetes within ASEAN territories (versus Australia and New Zealand).

We believe the company is continuing to work on obtaining Investigational New Drug (IND) clearance from the US FDA, which could permit the inclusion of US study sites in its ongoing Australian Phase III study. We continue to model that potential commercialisation for R327G in ABSSSI (including DFIs) in the US could occur in H2 CY28, but we may need to revisit our assumptions if IND clearance is not received by the end of Q1 CY27.

Altogether, we believe the company's near-term focus on advancing the DFI (and ABSSSI) indications for R327G provides a clear path to future revenues. The company's collaborations with the US Department of War for treatment of burn wound infections provide an additional lever for growth for topical R327G, as discussed in further detail in an earlier report.

Blinded R327G Indonesian results encouraging for upcoming unblinded readout

Recce on 20 October announced that a review of blinded study data from its ongoing Phase III registrational study of R327G for the treatment of DFIs indicates strong efficacy and an excellent safety and tolerability profile across the study. We believe this is highly encouraging as it suggests that the treatment arm (R327G) could be providing a therapeutic effect, consistent with previously reported data from an earlier Phase II DFI study. The ongoing Phase III study is a double-blinded, placebo-controlled design, with an initially planned total enrolment of up to 310 patients, where R327G is being compared to placebo.

In its blinded data update, Recce reports that a recent independent review of blinded data by Australian and international investigators showed encouraging safety and efficacy clinical outcomes among study participants, with a high proportion of patients experiencing either resolution or improvement in their infection. While the data is blinded (ie it is not yet known which patients received treatment or placebo), we believe the aggregate trends towards positive efficacy and infection resolution bode well for the study and suggest, in our view, a strong likelihood of differentiation between treatment and placebo. We reach this conclusion because in an acute infection population (such as DFIs), it would be highly unusual for a placebo topical treatment arm to lead to the positive efficacy findings reported to date.

Recce reports that 90 patients have been enrolled in the study and that the study's DMC will now perform an unblinded analysis on the data set corresponding to 75 patients. This analysis, potentially available by mid-November, will provide an initial indication of how R327G is performing compared to placebo. Following its analysis, the DMC will provide a recommendation, which could include advising the company to progress towards a regulatory submission and potential product registration (if supported by the safety and efficacy data). If this interim efficacy analysis is positive, showing a statistically significant efficacy result, it could pave the way for a regulatory approval application in Indonesia in Q4 CY26, with potential regulatory approval and launch in the country in the following weeks, as well as approvals and launches in other ASEAN countries in CY27.

Financials

Recce's FY26 financial results (for the period ending 30 June) were largely consistent with recent trends and our expectations, with the company reporting gross R&D expenditure of A$8.2m (vs A$10.4m in FY25) and SG&A costs of A$14.7m (vs A$17.3m). We believe the majority of R&D costs were allocated towards the ongoing Indonesian and Australian Phase III trials for R327G for the treatment of DFIs. Offsetting these costs were R&D research grants and subsidies, which came in at A$9.4m (including a A$0.5m grant from the US Department of War), up from A$7.0m in FY25. Altogether, Recce reported an operating loss of A$13.4m (vs A$20.4m in FY25) and free cash outflow of A$9.8m (vs A$20.6m), suggestive of stronger cost containment versus the prior year. As discussed in our prior note, Recce raised A$4.0m via an institutional share placement in late June and in subsequent weeks raised an additional A$2.4m

via a share purchase plan (SPP), resulting in total gross proceeds of A$6.4m from both initiatives.

More recently, in the company's Appendix 4C Update for the quarter ending 30 September (Q127), Recce confirmed it received A$3.6m in Research and Development Tax Incentives (RDTI) from the Australian Tax Office (ATO), and other government grants, bringing total FY25-related R&D rebates to c A$8.9m. Gross R&D expenses were $5.8m in the period, covering the ongoing Indonesian and Australian R327G clinical trials as well as other preclinical activities. Recce finished the period with A$1.0m in gross cash, but it expects to receive c A$7.5m under the Australian RDTI programme in the coming weeks. This RDTI cash rebate is expected to be based on the company's FY26 R&D spending, including costs covered under its Advance Overseas Finding (which relate primarily to costs incurred as part of the Phase III studies for R327G).

Recce ended FY26 (June 2026) with A$9.8m in gross debt, and it reported a repayment of A$0.058m in borrowings in the Q127 Appendix 4C. Hence, we estimate A$9.7m in gross debt and A$8.7m in net debt as of 30 September.

We maintain our product launch timing forecasts, as discussed in our prior note, for all major indications (DFIs and ABSSSI, sepsis/urosepsis, complex urinary tract infections, or cUTI, and burn wounds). Of note, we model launches of R327G in DFIs in Indonesia in late CY26, in the US and Australia in DFIs/ABSSSI in CY28 and for the IV R327 formulation in sepsis and cUTI in CY30 (see Exhibit 1).

Given the Q127 4C statement and recent trends, we have made adjustments to our FY27 forecasts. We continue to project a sharp year-on-year increase in R&D expenses, given the progression of the Australian Phase III DFI study and potential inclusion of US study sites. We also continue to anticipate that the company may seek to include the broader ABSSSI indication as part of its Australian and US development strategy for R327G. However, we have reduced our FY27 R&D forecast to A$30.7m, from A$38.6m previously, as we have pushed back our forecast for the start of a US Phase II study of intravenous (IV) R327 in cUTI/urosepsis to the end of FY27 or early FY28 (vs FY27 previously). We now model an FY27 free cash outflow of A$40.5m (vs A$46.6m previously).

We also introduce FY28 estimates, which are driven by continued R&D spending for the R327G candidate in DFI and burn wound infections, including US-based Phase III clinical trials for R327G, as well as a ramp up in clinical trial spending for IV R327 (in sepsis/urosepsis). We model FY28 R&D spending of A$47.1m and a free cash outflow of A $60.1m.

Assuming Recce continues to develop all four planned clinical-stage indications (ABSSSI including DFIs, burn wounds, sepsis/urosepsis and cUTI) in line with our timing expectations, we project it would need to raise A$115m in total net proceeds by FY29 (vs A$130m previously) before becoming sustainably cash flow positive. We continue to model these raises as illustrative debt.

Valuation

Our valuation is based on a relative rNPV calculation with a 12.5% cost of equity. We have rolled forward our estimates and included contributions from the announced Australian and New Zealand R327G DFI partnership agreement with Arrotex.

Exhibit 1: Recce Pharmaceuticals rNPV valuation

Product	Indication	Launch	Sales (A$m) in 2034	NPV (A$m)	Probability of success	rNPV (A$m)	rNPV/basic share (A$)
R327 (IV)	Sepsis	CY30	3,065	3,169.3	15%	458.1	1.50
R327 (IV)	Complicated UTI	CY30	391	380.0	15%	56.3	0.18
R327 (topical)	Burn wounds	CY28	295	442.6	20%	86.1	0.28
R327 (topical)	ABSSSI	H2 CY28	411	574.7	20%	113.7	0.37
R327 (topical)	Diabetic foot infections (ASEAN)	Q4 CY26	137	106.5	45%	47.9	0.16
R327 (topical)	Diabetic foot infections (MENA)	CY27	143	142.6	35%	49.9	0.16
R327 (topical)	Diabetic foot infections (Australia/New Zealand)	CY28	22	22.4	40%	8.9	0.03
Corporate costs				(154.1)		(154.1)	(0.50)
Estimated net cash/(debt) at 30 September 2026				(8.7)		(8.7)	(0.03)
Total equity value						658.4	2.15

Source: Edison Investment Research

Given the above, we now obtain an rNPV, including A$8.7m Q127 estimated net debt, of A$658.4m (or A$2.15 per share), versus A$657.3m (or A$2.19 per share) previously. The lower value per share is due to increased shares outstanding following the completion of the SPP.

As stated above, we project Recce would need to raise A$115m in proceeds between FY27 and FY29 to reach sustainable positive cash flows. While we model these raises as illustrative debt, if our projected funding need is raised

through equity issuances at the prevailing market price of c A$0.35, our effective value per share would decrease to A $1.21 (including cash raised via equity).

Depending on the availability of capital, the company may decide to prioritise certain programmes, which could affect the timing of launches in non-prioritised indications and our overall valuation. Our funding model assumes Recce will advance all four programmes in parallel. However, if the company prioritises R327G in ABSSSI and DFIs and puts its remaining development programmes on hold until the initial R327G commercial approvals, its overall funding need would reduce as it could then apply post-launch commercial revenue towards resuming R&D and product development activities in the remaining targeted indications. 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.

Exhibit 2: Financial summary

A$(000)	2021	2022	2023	2024	2025	2026	2027e	2028e
Year end 30 June	IFRS	IFRS	IFRS	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS								
Revenue	1,857	3,085	4,311	4,906	6,971	9,378	6,771	19,426
Cost of Sales	0	0	(0)	(0)	(0)	(0)	(0)	(0)
Gross Profit	1,857	3,085	4,311	4,906	6,971	9,378	6,771	19,426
Sales, General & Administrative	(9,511)	(7,677)	(9,779)	(14,526)	(17,265)	(14,734)	(14,279)	(22,001)
Net Research & Development	(5,657)	(6,285)	(7,330)	(7,159)	(10,383)	(8,151)	(30,714)	(47,143)
EBITDA	(13,311)	(10,878)	(12,797)	(16,778)	(20,677)	(13,508)	(38,223)	(49,718)
Depreciation & amortisation of intangible assets	0	0	0	0	0	0	0	0
Depreciation, amortisation & other	(296)	(188)	(217)	(367)	(356)	(356)	(862)	(440)
Normalised Operating Profit (ex. amort, SBC, except.)	(8,389)	(10,809)	(12,689)	(17,125)	(19,696)	(12,798)	(39,084)	(15,687)
Operating profit before exceptionals	(13,607)	(11,065)	(13,014)	(17,145)	(21,033)	(13,864)	(39,084)	(50,159)
Exceptionals including asset impairment	0	0	54	143	626	453	0	0
Other	0	0	0	0	0	0	0	0
Reported Operating Profit	(13,607)	(11,065)	(12,960)	(17,002)	(20,406)	(13,411)	(39,084)	(50,159)
Net Finance income (costs)	94	79	(117)	(660)	(1,022)	(1,550)	(2,113)	(10,264)
Profit Before Tax (norm)	(13,513)	(10,986)	(13,131)	(17,805)	(22,054)	(15,414)	(41,197)	(60,423)
Profit Before Tax (FRS 3)	(13,513)	(10,986)	(13,077)	(17,662)	(21,428)	(14,961)	(41,197)	(60,423)
Tax	0	0	0	0	0	0	0	0
Profit After Tax and minority interests (norm)	(13,513)	(10,986)	(13,131)	(17,805)	(22,054)	(15,414)	(41,197)	(60,423)
Profit After Tax and minority interests (FRS 3)	(13,513)	(10,986)	(13,077)	(17,662)	(21,428)	(14,961)	(41,197)	(60,423)
Average Basic Number of Shares Outstanding (m)	155.4	174.1	174.0	177.1	237.0	289.2	302.7	305.9
EPS - normalised (A$)	(0.09)	(0.06)	(0.08)	(0.10)	(0.09)	(0.05)	(0.14)	(0.20)
EPS - normalised and fully diluted (A$)	(0.09)	(0.06)	(0.08)	(0.10)	(0.09)	(0.05)	(0.14)	(0.20)
EPS - (IFRS) (A$)	(0.09)	(0.06)	(0.08)	(0.10)	(0.09)	(0.05)	(0.14)	(0.20)
Dividend per share (A$)	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
BALANCE SHEET								
Fixed Assets	501	439	608	1,233	1,028	1,412	722	384
Intangible Assets	0	0	0	0	0	0	78	78
Tangible Assets	501	439	608	1,233	1,028	1,412	644	306
Investments in long-term financial assets	0	0	0	0	0	0	0	0
Current Assets	21,181	12,185	1,947	5,136	11,386	7,116	23,913	23,828
Short-term investments	0	0	0	0	0	0	0	0
Cash	20,873	11,582	1,562	4,415	10,449	2,694	19,491	19,406
Other	308	603	386	721	937	4,421	4,421	4,421
Current Liabilities	(1,078)	(2,447)	(4,850)	(15,070)	(6,129)	(16,322)	(16,322)	(16,322)
Creditors	(1,078)	(2,447)	(1,802)	(5,381)	(4,603)	(14,848)	(14,848)	(14,848)
Short-term borrowings	0	0	(3,048)	(9,689)	(1,527)	(1,474)	(1,474)	(1,474)
Long-Term Liabilities	(100)	(115)	(295)	(824)	(9,337)	(8,929)	(63,871)	(123,871)
Long-term borrowings	0	0	0	0	(8,599)	(8,301)	(63,243)	(123,243)
Other long-term liabilities	(100)	(115)	(295)	(824)	(739)	(628)	(628)	(628)
Net Assets	20,504	10,061	(2,589)	(9,524)	(3,052)	(16,723)	(55,559)	(115,982)
CASH FLOW STATEMENT								
Operating Income	(13,607)	(11,065)	(12,960)	(17,002)	(20,406)	(13,411)	(39,084)	(50,159)
Movements in working capital	144	1,532	(152)	4,266	(707)	0	0	0
Net interest and financing income (expense)	94	79	(117)	(660)	(1,022)	(1,550)	(2,113)	(10,264)
Depreciation & other	296	188	217	367	356	356	862	440
Taxes and other adjustments	5,218	256	325	20	1,337	4,713	(0)	(0)
Net Cash Flows from Operations	(7,856)	(9,010)	(12,687)	(13,009)	(20,442)	(9,892)	(40,335)	(59,983)
Capex and capitalised expenditures	(76)	(40)	(39)	(142)	(26)	(62)	(93)	(102)
Acquisitions/disposals	0	0	0	0	(181)	187	(78)	0
Interest received & other investing activities	0	0	0	0	(237)	(1)	0	0
Net Cash flows from Investing activities	(76)	(40)	(39)	(142)	(444)	124	(171)	(102)
Net proceeds from share issuances	26,338	287	102	10,583	26,613	3,669	2,158	0
Net movements in long-term debt	0	0	0	5,886	591	0	54,942	60,000
Dividends	0	0	0	0	0	0	0	0
Other financing activities	(215)	(528)	2,604	(464)	(284)	(1,655)	0	0
Net Cash flows from financing activities	26,123	(240)	2,706	16,004	26,920	2,014	57,100	60,000
Effects of FX on Cash & equivalents	0	0	0	0	0	0	203	0
Net Increase (Decrease) in Cash & equivalents	18,191	(9,291)	(10,020)	2,854	6,034	(7,754)	16,797	(85)
Cash & equivalents at beginning of period	2,682	20,873	11,582	1,562	4,415	10,449	2,694	19,491
Cash & equivalents at end of period	20,873	11,582	1,562	4,415	10,449	2,694	19,491	19,406
Closing net debt/(cash)	(20,873)	(11,582)	1,487	5,274	(324)	7,080	45,225	105,310
Lease debt	127	75	251	461	643	667	667	667
Closing net debt/(cash) inclusive of IFRS16 lease debt	(20,746)	(11,507)	1,737	5,735	319	7,747	45,892	105,977
Free cash flow	(7,932)	(9,051)	(12,726)	(13,151)	(20,649)	(9,767)	(40,506)	(60,085)

Source: Company accounts, Edison Investment Research

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