

# Recce Pharmaceuticals

B POM clearance to start Phase III R327G study

Clinical trial clearance

Pharma and biotech

17 December 2024

**Price** **A\$0.47**

**Market cap** **A\$109m**

US\$0.65/A\$

Estimated net debt (A\$m) at 30 September 2024 3.5

Shares in issue 231.9m

Free float 90%

Code RCE

Primary exchange ASX

Secondary exchange Frankfurt: R9Q, OTC: RECEF

Recce received [approval](#) from the Indonesian Drug and Food Regulatory Authority, Badan POM (BPOM), to start its registrational Phase III study in Indonesia of RECCE® 327 topical gel (R327G) in diabetic foot infections (DFIs). This was the final hurdle that needed to be overcome before study enrolment can proceed, which is expected to start before the end of 2024. Top-line data from the 300-patient double-blinded Phase III study (with 200 patients in the R327 arm and 100 on placebo) are anticipated in late 2025. If positive, we expect Recce would be able to launch R327G in South-East Asia in H2 CY26, potentially marking the company's transition to a commercial stage.

Year end	Revenue** (A\$m)	PBT* (A\$m)	EPS* (A\$)	DPS (A\$)	P/E (x)	Yield (%)
06/23	4.3	(13.1)	(0.08)	0.0	N/A	N/A
06/24	4.9	(17.8)	(0.10)	0.0	N/A	N/A
06/25e	10.1	(16.2)	(0.07)	0.0	N/A	N/A
06/26e	6.0	(71.9)	(0.31)	0.0	N/A	N/A

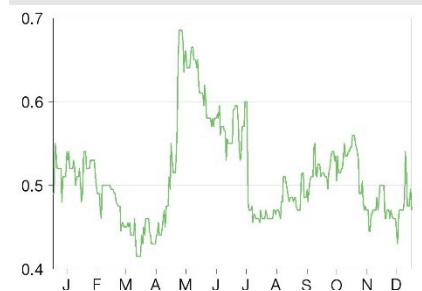
Note: \*PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments. \*\*Revenue figures reflect gross revenues.

DFIs are a frequent complication in patients who have diabetes mellitus that is not adequately controlled and are the most common complication from diabetes requiring hospitalisation. About 2–4% of patients with diabetes will experience foot ulceration each year, of which 50–60% will result in DFIs. We believe the prevalence of diabetes in [ASEAN](#) countries is c 47 million people, marking a c A\$50m (annual) DFI revenue opportunity for Recce, as summarised in [our prior note](#).

Recce is receiving significant funding and infrastructure support from key Indonesian stakeholders, including the Indonesian Ministry of Health, for the registrational Phase III DFI programme as well as from its previously announced [strategic collaboration](#) and memorandum of understanding in South-East Asia with Indonesian biomedical company PT Etana Biotechnologies. Consequently, Recce expects its total cost to complete the study will be US\$2m, not including the effects from the 43.5% R&D rebate scheme under the company's advanced overseas finding status with the Australian government. Hence, the net cost to Recce may only be c US\$1.2m.

Recce also reiterated that it is on track to complete its [open-label Phase II study assessing R327G](#) as a treatment for acute bacterial skin and skin structure infections (ABSSSI) before the end of 2024. It [reported in November 2024](#) that it has dosed 20 patients out of an expected total enrolment target of 30 and that all patients dosed to date (excluding one patient withdrawal) had met the primary endpoint of either a complete cure of their presenting condition or a significant improvement following treatment with R327G. Recce reiterated that it expects to start a Phase III ABSSSI study in Australia and New Zealand in H1 CY25. We anticipate potential commercialisation for R327G in ABSSSI in CY28. Altogether, we believe the company's near-term focus on advancing the ABSSSI and DFI indications for R327G are providing a clear path to future revenues.

## Share price performance



## 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, acute bacterial skin and skin structure infections, burn wound infections and urinary tract infections.

## Analyst

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