Recce Pharmaceuticals

RCE.AX

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A research platform of MST Financial

27 October 2026

Arrotex secured for ANZ launch

Exclusive Arrotex licensing & commercialisation agreement. On 22 Oct 26, RCE signed a binding agreement with Arrotex Pharmaceuticals, Australia's largest generic and private-label pharmaceutical company. Arrotex will register and commercialise R327G for the treatment of diabetic foot infections (DFI) in Australia and New Zealand (ANZ). Arrotex's TGA filing is contingent on a FDA (or equivalent) approval, effectively making the FDA pathway RCE's priority. We assume that RCE will cross-submit for FDA and TGA approval once the Australian Ph3 trial is complete end CY2027. As such, we estimate FDA and TGA approval to occur sometime in 1HCY29e (i.e. 2H29e). MSTe first R327G Australia revenue in 1H30e via Arrotex.

Indonesian Ph3 past halfway to interim readout. As of 20 Oct 26, RCE had enrolled 90 patients in its Indonesian Phase 3 trial for DFI. Interim data readout remains unchanged at 155 patients enrolled and treated. Therefore, RCE is now 58% advanced towards interim, a significant catalyst for the stock to reprice. With 65 patients still to be enrolled at current run-rate of 4.5 patients/wk, MSTe 14-15 weeks (i.e. ~3.5-4 mths) until interim data readout. MSTe Indonesian Ph3 for DFI interim readout delayed to Feb 27 (vs management expectations 2Q FY27 and previously MSTe 1H27).

Avenue Capital debt terms extended. On 16 Oct 26, RCE extended its Avenue Capital facility's interest-only period to Dec 26, with two further options to Sep 27, and its Tranche 2 (US$5m) draw period to Dec 26. The latter two are subject to clinical and funding milestones. In return, Avenue receives 493,103 warrants (exercisable at A$0.29/share), lifting MSTe total Avenue warrants to ~5.44m. We estimate this represents minor dilution of ~2% of 289.2m shares on issue at end FY26.

Investment Thesis

Late-stage novel anti-infectives platform (R327) for multiple indications. RCE's new class of fully synthetic polymer delivers a unique and universal mechanism of action to a broad spectrum of infections including multi-drug-resistant infections. Its FDA Qualified Infectious Disease Product designation (R327 IV only) offers fast-track approval and 10 years market exclusivity.

Two parallel Ph3 trials in operation. Upcoming interim readout for the Indonesian registrational Ph3 R327G DFI trial is expected for MSTe 2HFY27. Australian registrational Ph3 R327G DFI trial received HREC approval in Jun 26 and targeting study completion by late 1H28.

MENA & ANZ commercialisation & licensee established. RCE has outlined commercialisation pathway into two key markets: 1) Middle East & North Africa (~1m DFI population) via a licensing term sheet, and 2) Australia/ New Zealand via a binding Arrotex agreement.

Valuation/Risks

We estimate a risk-adjusted NPV-based valuation of A$2.05/share (previously A$2.55) for RCE, implying a potential upside of ~540% to the last traded stock price. Our valuation reflects a pro-forma cash balance of A$22.6m at 21 Jul 26. We have delayed first revenue in Indonesia to 1H28e, pushed first MENA revenue to 2H28e, forecast first ASEAN (ex-Indonesia) revenue in 1H29e and anticipate first revenue in Australia to occur in 1H30e. We also updated our AUD/USD FX rate to 0.71 (vs previously 0.67).

Key risks: 1) outcome from clinical trials, 2) delays in patient enrolment & development timelines, 3) regulatory approval delays or rejection, 4) funding shortfalls, 5) manufacturing, distribution & commercialisation execution risk.

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Recce Pharmaceuticals

Recce Pharmaceuticals is an advanced Ph3-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.

Valuation	**A$2.05** *(from A$2.55)*
Current price	**A$0.32**
Market cap	**A$96m**
Cash on hand	**A$22.6m** *(30 June 2026 proforma)*

Upcoming Catalysts

Period	
2HFY27	Interim data Ph3 R327G (Indonesia)
2HFY27	Interim data Ph3 R327G (Australia)
2HFY28	MENA R327G commercialisation

RCE Share Price (A$)



This report has been prepared and issued by the named analyst of MST Access in consideration of a fee payable by: Recce Pharmaceuticals (RCE.AX)

Report prepared by MST Access, a registered business name of MST Financial Services Limited ABN 54 617 475 180 AFSL 500 557.

Figure 1: RCE financial summary

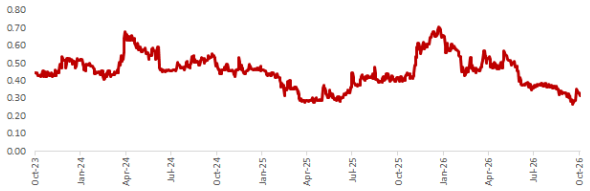
Recce Pharmaceuticals — **RCE-AU**

Year end 30 June, AUD unless otherwise noted

MARKET DATA

Price	**$**	**0.32**
52 week high / low	**$**	0.73/0.265
Valuation	**$**	**2.05**
Market capitalisation	$m	96
Shares on issue (basic)	**m**	356.5
Options / rights	m	16.0
Other equity	m	0.0
Shares on issue (diluted)	**m**	**372.5**

12-MONTH SHARE PRICE PERFORMANCE (A$)



INVESTMENT FUNDAMENTALS		FY24A	FY25A	FY26A	FY27e	FY28e
Reported NPAT	$m	(17.7)	(21.4)	(15.0)	(11.6)	6.1
Underlying NPAT	**$m**	**(17.7)**	**(21.4)**	**(15.0)**	**(11.6)**	**6.1**
Reported EPS (diluted)	¢	(10.0)	(9.0)	(5.2)	(4.0)	1.9
EPS Underlying (diluted)	**¢**	**(10.0)**	**(9.0)**	**(5.2)**	**(4.0)**	**1.9**
Growth	%					
Underlying PER	x	**nm**	**nm**	**nm**	**nm**	**16.7**
Operating cash flow per share	¢	-5.6	-7.1	-3.4	-3.6	1.7
Free cash flow per share	¢	-5.7	-7.2	-3.4	-3.6	1.7
Price to free cash flow per share	**x**	**nm**	**nm**	**nm**	**nm**	**18.4**
FCF Yield	%	nm	nm	nm	nm	5.4%
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**	**92.7**	**88.8**	**97.0**	**98.2**	**82.1**
EV/EBITDA	x	(5.5)	(4.4)	(7.2)	(8.8)	9.4
EV/EBIT	x	(5.4)	(4.3)	(7.2)	(8.7)	9.5
Price to book (NAV)	x	(7.7)	(29.8)	(5.4)	(5.6)	(50.4)
Price to NTA	x	(7.7)	(29.8)	(5.4)	(5.6)	(57.8)

KEY RATIOS		FY24A	FY25A	FY26A	FY27e	FY28e
EBITDA margin	%	nm	nm	nm	nm	35.6
EBIT margin	%	nm	nm	nm	nm	35.2
NPAT margin	%	nm	nm	nm	nm	24.7
ROE	%	nm	nm	nm	nm	(272.3)
ROA	%	nm	nm	nm	nm	26.1
Net tangible assets per share	$	(0.0)	(0.0)	(0.1)	(0.1)	(0.0)
Book value per share	$	(0.0)	(0.0)	(0.1)	(0.1)	(0.0)
Net debt/(cash)	$m	(3.6)	(7.5)	0.6	1.9	(14.2)
Interest cover/ (EBIT/net interest)	x	nm	nm	nm	nm	(3.4)
Gearing (net debt/EBITDA)	x	nm	nm	(0.0)	(0.2)	nm
Leverage (net debt/(net debt + equit	x	nm	nm	(0.0)	(0.1)	nm

DUPONT ANALYSIS		FY24A	FY25A	FY26A	FY27e	FY28e
Net Profit Margin	%	nm	nm	nm	nm	24.7
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 complet
R327 (topical)	Burn wound infection	In development with DoD
R327 (topical)	Diabetic foot infections (Indonesia)	Phase 3 underway
R327 (topical)	Diabetic foot infections (Australia)	Phase 3 underway
R327 (inhalation)	Hospital/Ventilator Acquired Pneum	Preclinical
R435 (oral)	Helicobacter pylori in stomach ulcer	Preclinical
Anti-viral programs	**Indication**	**Status**
R327 (nasal)	SARS-CoV-2 & other viral infections	Preclinical
R529	Viral infections	Preclinical

HALF YEARLY DATA		2H24	1H25	2H25	1H26	2H26
Total Revenue	$m	2.7	6.9	0.7		
Operating expenses	$m	(12.4)	(14.7)	(13.3)		
EBITDA	$m	(9.8)	(7.7)	(12.6)		
EBIT	$m	(9.8)	(7.8)	(12.7)		
PBT	$m	(9.7)	(7.7)	(12.6)		
Reported NPAT	$m	(9.7)	(7.7)	(12.6)		

PROFIT AND LOSS		FY24A	FY25A	FY26A	FY27e	FY28e
Revenue	**$m**	**0.0**	**0.0**	**0.0**	**0.0**	**19.0**
Other income	$m	5.0	7.6	9.8	6.2	5.5
Total Revenue	**$m**	**5.0**	**7.6**	**9.8**	**6.2**	**24.6**
Operating expenses	$m	(22.0)	(28.0)	(23.3)	(17.4)	(15.8)
EBITDA	**$m**	**(17.0)**	**(20.4)**	**(13.5)**	**(11.2)**	**8.8**
Depreciation & Amortisation	$m	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)
EBIT	**$m**	**(17.1)**	**(20.4)**	**(13.5)**	**(11.3)**	**8.7**
Net interest	$m	(0.6)	(1.0)	(1.4)	(0.3)	(2.6)
Pretax Profit	**$m**	**(17.7)**	**(21.4)**	**(15.0)**	**(11.6)**	**6.1**
Tax expense	$m	0.0	0.0	0.0	0.0	0.0
Reported NPAT	**$m**	**(17.7)**	**(21.4)**	**(15.0)**	**(11.6)**	**6.1**
Underlying NPAT	$m	**(17.7)**	**(21.4)**	**(15.0)**	**(11.6)**	**6.1**
End of year shares	m	231.9	288.4	289.2	322.8	356.5

GROWTH PROFILE		FY24A	FY25A	FY26A	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	FY26A	FY27e	FY28e
Cash	$m	4.4	10.4	2.7	1.4	17.5
Receivables	$m	0.2	0.4	3.9	3.9	3.9
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**	**7.1**	**5.9**	**22.0**
PPE	$m	0.4	0.4	0.8	0.7	0.7
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**	**1.4**	**1.4**	**1.3**
Total assets	**$m**	**6.4**	**12.4**	**8.5**	**7.2**	**23.3**
Trade and other payables	$m	14.4	3.0	12.6	12.6	12.6
Borrowing and leases	$m	0.2	2.5	2.9	2.9	2.9
Other	$m	0.5	0.6	0.8	0.8	0.8
Current liabilities	**$m**	**15.1**	**6.1**	**16.3**	**16.3**	**16.3**
Borrowing and leases	$m	0.6	0.4	0.4	0.4	0.4
Other liability	$m	0.2	8.9	8.5	8.5	8.5
Non current liabilities	**$m**	**0.8**	**9.3**	**8.9**	**8.9**	**8.9**
Total liabilities	**$m**	**15.9**	**15.5**	**25.3**	**25.3**	**25.3**
Net assets	**$m**	**(9.5)**	**(3.1)**	**(16.7)**	**(18.0)**	**(1.9)**
Share capital	$m	54.8	81.5	81.7	91.7	101.7
Retained earnings	$m	(70.1)	(91.5)	(101.3)	(112.9)	(106.8)
Other	$m	5.7	7.0	2.9	2.9	2.9
Total equity	**$m**	**(9.5)**	**(3.1)**	**(16.7)**	**(18.3)**	**(2.2)**

CASH FLOW		FY24A	FY25A	FY26A	FY27e	FY28e
Net loss for period	**$m**	**(17.7)**	**(21.4)**	**(15.0)**	**(11.6)**	**6.1**
Depreciation & Amortization	$m	0.1	0.1	0.1	0.1	0.1
Changes in working capital	$m	4.3	(0.7)	3.1	0.0	0.0
Other	$m	0.3	1.6	1.9	0.0	0.0
Operating cash flow	**$m**	**(13.0)**	**(20.4)**	**(9.9)**	**(11.5)**	**6.2**
Payments for PPE	$m	(0.1)	(0.0)	(0.1)	(0.1)	(0.1)
Other	$m	0.0	(0.4)	0.2	0.0	0.0
Investing cash flow	**$m**	**(0.1)**	**(0.4)**	**0.1**	**(0.1)**	**(0.1)**
Equity	$m	10.5	26.6	3.7	10.0	10.0
Borrowing and Lease liability r	$m	5.6	0.3	(1.7)	0.0	0.0
Other	$m	(0.0)	(0.0)	0.3	0.0	0.0
Financing cash flow	**$m**	**16.0**	**26.9**	**2.3**	**10.0**	**10.0**
Cash year end	**$m**	**4.4**	**10.4**	**3.0**	**1.4**	**17.5**
Free cash flow	**$m**	**(13.2)**	**(20.9)**	**(9.8)**	**(11.5)**	**6.1**

Source: Company reports, MSTe

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Australia Ph3 for DFI

Arrotex, exclusive licensing and commercialisation partner

On 22 Oct 26, RCE signed a binding, exclusive licensing and commercialisation agreement with Arrotex Pharmaceuticals. Arrotex is Australia's largest generic and private-label pharmaceutical company. Arrotex sells a mix of generic prescription medicine, private-label over-the-counter (OTC) products and licensed brands. In CY2023, Arrotex had ~65% share of the Australian generic pharmaceuticals market (AFR).

Key terms of the agreement:

- Arrotex will register and commercialise R327G for the treatment of DFI in Australia and New Zealand (ANZ).
- Application for R327G TGA approval contingent on approval by the FDA, EMA or another TGA-recognised regulator.
- RCE will manufacture and exclusively supply R327G to Arrotex.
- RCE will receive a supplier fee (RCE's cost plus margin) and a significant, but undisclosed, share of gross margin on ANZ sales of R327G.

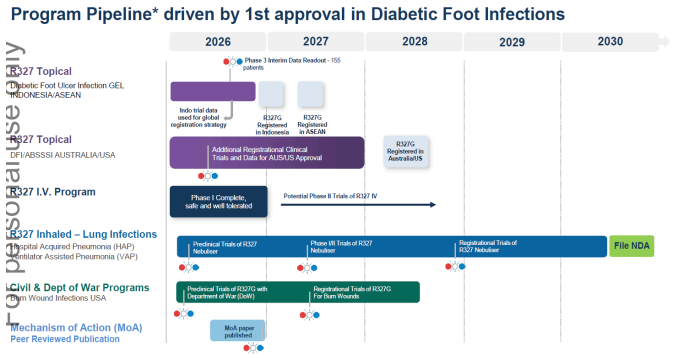
As at 22 Jun 26, the Australian Phase 3 trial had dosed 18 of a possible 200 total patients. In the Program Pipeline chart (**Figure 2** below) from the General Meeting (2 Sep 26), we note that management is now expecting completion of the Ph3 trial to be around end CY2027. Consequently, Australia/ US registration is guided to be ~mid-CY2028. This has been brought forward from the Jun 26 investor presentation (**Figure 3** below) where interim data readout was anticipated for early CY2028, with registration in 2H CY28.

In order to file for FDA approval, we expect RCE will submit an Investigational New Drug application (IND) early in CY2028. Our understanding is that RCE has been working closely with the FDA. They have also been advised by regulatory experts that Australian and Indonesian datasets combined could be enough for an FDA submission.

We conservatively assume that RCE will cross-submit for FDA and TGA approval once the Australian Ph3 trial is complete at the end of CY2027. The average standard FDA review timeframe is ~10 months with an additional 60-day filing period. As such, we estimate FDA and TGA approval to occur sometime in 1HCY29e (i.e. 2H29e). With Arrotex now secured as a commercialisation partner, we assume first revenue in Australia to occur in 1H30 following TGA approval in 2H29.

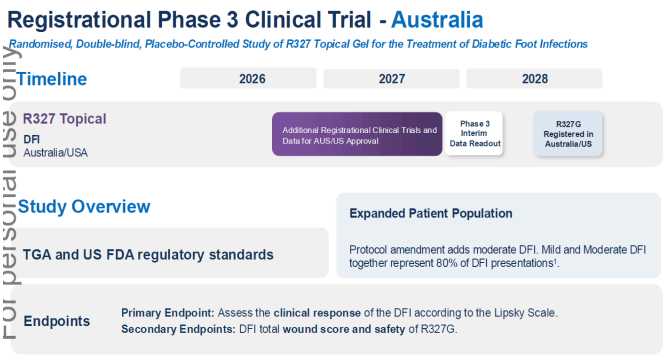
Overall, we view the binding agreement with Arrotex to be incrementally net positive as it de-risks RCE's ANZ launch of R327G at no commercialisation cost. However, it does not include upfront or milestone payments, and ties ANZ registration to an FDA (or equivalent) approval where risk remains around the need for additional datasets.

Figure 2: RCE's program pipeline (2 Sep 26)



Source: Company presentation

Figure 3: RCE's Australian Ph3 trial timeline (26 Jun 26)



Source: Company presentation

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Indonesian Ph3 for DFI

Upcoming unblinded DMC review

On 20 Oct 26, RCE shared an update that its Indonesian Phase 3 trial had undergone a review of blinded data by clinical experts and a statistician. The review highlighted a *"very positive safety profile"*. Management also stated that the review indicated *"strong efficacy"*. However, as the data is blinded and the data pool is a mix of gel and placebo patients, strong efficacy cannot be directly attributed to R327G.

Management also shared that a dataset of 75 patients has been submitted to the independent Data Monitoring Committee (DMC). The DMC will unblind the datasets and is expected to provide recommendations to RCE by mid-Nov 26 at the earliest.

The DMC typically assesses trial data prior to major clinical milestones for:

- **Safety.** DMCs routinely look at unblinded safety data during a trial to protect patients.
- **Early efficacy.** If data presents to be very efficacious, the trial can stop early and move to filing for registration earlier.
- **Futility.** To stop a trial early if the drug isn't working, mitigating further cash burn and patient exposure.
- **Sample size.** Tests whether the planned number of 310 total patients still has statistical power.

DMC's recommendation will indicate whether to: 1) stop the trial early for early registration, 2) continue the trial, 3) amend the trial design or 4) halt the trial due to futility.

Trial passes halfway to interim readout

As of 20 Oct 26, RCE had enrolled 90 patients in its Indonesian Phase 3 trial for diabetic foot infections (DFI). We note that the interim data readout remains unchanged and requires 155 patients enrolled and treated. Therefore, RCE is now 58% advanced towards interim readout, a significant catalyst for the stock to reprice.

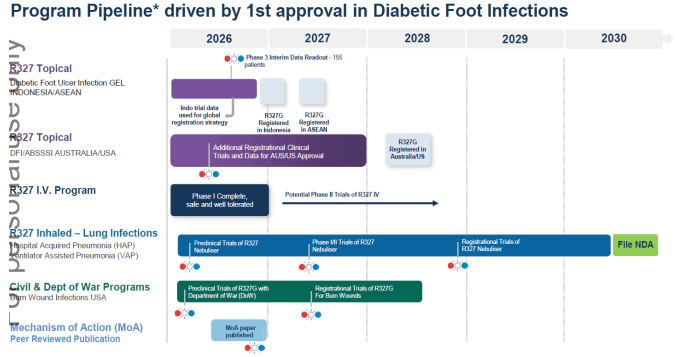
Enrolment is currently run-rating at 4.5 patients per week. With 65 patients still to be enrolled and dosed, we estimate that it could take 14 to 15 weeks (i.e. ~3.5 to 4 months) until interim data readout. MSTe interim data readout for RCE's Indonesian Ph3 for DFI could fall in Feb 27.

Contrastingly, the Program Pipeline chart (**Figure 4** below) shared by management at the General Meeting on the 2 Sep 26 is indicative of a 4Q CY26 interim data readout. We note that this had been delayed from 3Q CY26 as stated in RCE's Jun 26 investor presentation (**Figure 5** below).

An acceleration in patient enrolment could enable interim readout date to fall within 2Q FY27. We calculate this would require 8 to 10 patients enrolled per week. Alternatively, as mentioned in the prior section, the DMC's mid-Nov 26 findings on unblinded data could also point to earlier registration filing for R327G, supported by robust results across both primary and key secondary endpoints.

We remain conservative in our forecasts and adjust for interim data readout to occur in Feb 27 (2H27e). Consequently, we expect RCE will register R327G with Indonesian regulators (BPOM) supported by interim data. Under an expedited regulatory review process (30-60 days), we expect first revenue in Indonesia to occur in late 1H28e.

Figure 4: RCE's program pipeline (2 Sep 26)



Source: Company presentation

Figure 5: RCE's Indonesian Ph3 trial timeline (26 Jun 26)



Source: Company presentation

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Avenue Capital debt facility extended

RCE had established a debt facility (of up to US$20m, cash interest rate of 12.75%) with Avenue Capital in Jun 25. On 16 Oct 26, the company announced amendments to debt facility terms to support ongoing Ph3 studies and better align debt with key operational milestones.

Amended terms include:

- Baseline interest-only period extended by 3 months to 31 Dec 26
- Two subsequent interest-only extension options (through to 30 Sep 27). Contingent on RCE achieving defined capital raising targets and positive clinical milestones within its ongoing Ph3 studies.
- Availability period to drawn down on Tranche 2 (US$5m) extended to 31 Dec 26 (vs previously 30 Sep 26). Subject to achieving clinical and funding milestones.

In consideration for the amendments, RCE will issue Avenue Capital 493,103 warrants, amounting to US$100,000 (A$143,000), with an exercise price of A$0.29 and expiry date of 15 Oct 31.

We estimate ~4.95m warrants were issued at the facility's inception (Jun 25), at an exercise price of A$0.31/share. MSTe total warrants issued to Avenue Capital now sits at ~5.44m. We expect minor dilution of ~2% of 289.2m shares on issue as at end FY26.

Forecast changes

Following RCE's updates we made the following forecast changes:

- **Indonesia R327G for DFI.** We have delayed first revenue in Indonesia to 1H28e as we expect slower patient enrolment (on current run-rate of 4.5 patients per week) could delay interim data readout till 2H27e (vs management expectations of late 1H27e).
- **MENA R327G for DFI.** We delayed first revenue to 2H28e, as approval and initial market launch in Saudi Arabia is dependent on the Indonesia Ph3 outcome (MSTe Indonesia Ph3 interim data readout delayed to 2H27e). We expect RCE's licensing term sheet (May 26) with a large MENA pharmaceutical company should facilitate immediate entry into Saudi Arabia post-regulatory approval.
- **ASEAN (ex-Indonesia) R327G for DFI.** We forecast first ASEAN (ex-Indonesia) revenue in 1H29e, following Indonesian approval (MSTe 1H28e) and assuming RCE prioritises MENA entry given limited resources.
- **Australia R327G for DFI.** With the new Arrotex partnership, we anticipate first revenue to occur in 1H30e as registering for TGA approval will follow a FDA-equivalent approval (MSTe 2H29e).
- **AUD/USD FX rate.** We updated our AUD/USD FX rate to the last 3-month average of 0.71.

Valuation

MSTe RCE at A$2.05/share (previously A$2.55)

We estimate a risk-adjusted NPV-based valuation of A$2.05/share on a fully diluted basis for Recce Pharmaceuticals, implying a potential upside of ~540% to the last traded stock price. Our valuation reflects RCE's FY26 financials reported on 31 Aug 26 and incorporates ~16m options and performance rights outstanding (including the new warrants issued to Avenue Capital on 26 Oct 26), exercisable at various prices.

Our valuation reflects a pro-forma cash balance of A$22.6m at 21 Jul 26, and assumes additional capital raises of A$20m at a stock price of A$0.30/share (10% discount to last traded RCE stock price of $0.33/share) over FY27-FY28e. Pro-forma cash balance includes a tax refund of A$3.7m, estimated R&D tax rebate for FY26 of ~A$7.5m, and potential total capital raise funding of A$8m, net of fees.

A discount rate of 12.5% and AUD/USD FX rate of 71c is used in our risk-adjusted NPV valuation for RCE.

Figure 6: rNPV-based valuation for RCE

Product	Status	Indications	Dose (delivery)	Expected launch	Peak sales (US$m)	NPV*(US$m)	Likelihood of approval	rNPV (A$m)
R327G	Phase 3	Diabetic foot infections (DFI)	Topical	late FY28	109	257	45%	164
R327	Various stages	Other disease indications	Topical, IV and aerosol	CY28 onwards	n/a	2563	various	575
							Cash position as at 21 Jul 2026 (A$)	22.6
							Diluted shares outstanding	373
							rNPV/share (A$)	**2.05**

Source: MSTe

Near-term catalysts

- **2HFY27.** Indonesia Ph3 for DFIs interim data read-out at 155 patients dosed. Subsequent expedited regulatory review with commercial approval expected in 1H28.
- **2HFY27.** Australia R327G Ph3 trial for DFI interim data readout following treatment of 100 patients.
- **2HFY28.** MENA commercialisation of R327G pending: 1) Indonesian Phase 3 interim data and BPOM (Indonesia FDA equivalent) regulatory approval, 2) finalisation of definitive exclusive licensing agreement with Middle Eastern pharmaceutical licensee, and 3) Saudi Arabia regulatory approval of R327G using Indonesian trial data.

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Risks

- **Clinical trial risk.** Potential failure of key assets to demonstrate adequate safety or efficacy in late-stage trials. This could delay or halt further development and erode long-term value for the company.
- **Patient enrolment and timeline delays.** Slow recruitment and site activation can delay data read-outs, increase trial costs and hinder anticipated cashflow generation.
- **Regulatory approval risk.** Regulatory agencies may demand additional data or deny approval, extending timelines and reducing the probability of success. This can delay first revenue and erode long-term value for the company.
- **Funding and capital structure.** Ongoing drug development requires numerous or emergency capital raises. Any funding shortfall or adverse market conditions can resulting in shareholder dilution or increases going concern risk.
- **Manufacturing and supply chain.** Challenges in scaling and validating manufacturing, or disruptions with key suppliers can delay launch and constrain product availability.
- **Commercialisation and market adoption.** Post-approval, slow physician or patient uptake, reimbursement constraints and formulary access hurdles can delay revenue ramp and compress margins.

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Rita Fung 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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