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# Recce Ltd (ASX: RCE)

# Ahead of schedule for Phase 1 human tests

- Since listing in January 2016, in-vitro and animal cell testing has demonstrated the antibiotic as well as anti-cancer (and most recently anti-viral) properties of RCE's patented, synthetic-polymer RECCE® antibiotics. Tests have also indicated the drugs' efficacy without toxicity (including genetic toxicity).
- RCE is currently doing pre-clinical (animal) testing on drug safety and efficacy. The tests will be largely directed at determining the ability of the RECCE® 327 antibiotic to treat sepsis (blood infection).
- Between now and early 2017, RCE is targeting to complete 19 specific tests (around one every two weeks). Thus, we forecast a steady news flow emanating from the group over the next 7-8 months.
- Predicated on the results from the pre-clinical tests, RCE is targeting to submit the key Investigational New Drug ("IND") application to the US Food and Drug Administration ("FDA") in March 2017. Note: an IND is a request for authorisation from the FDA to administer an investigational drug or biological product to humans.
- The testing, which is fully funded (RCE's cash balance A\$3.59m as at the end of June 2016) will be carried out in contracted laboratories in the US.
- Depending on the application approval process, we expect that RCE could then be in a position to commence with clinical human trials (Phase 1- Safety) by mid-2017.
- Relative to the initial target of commencing Phase 1 testing around two
  years after the group's IPO in January 2016, it appears that RCE is some
  six months ahead of its development timeline. If correct, this would reflect
  well on management's ability to progress the project.
- Successfully completing pre-clinical trials and moving to Phase 1 testing
  is an important step in the drug development process, and typically acts
  as a significant share price catalyst.
- Based on a global antibiotic and oncology drugs market of US\$40bn (2014) and US\$130bn (2016) respectively, we estimate that the potential NPV of a royalty/licencing stream to RCE for its RECCE® antibiotics could indicatively exceed A\$1bn. See research "Antibiotic plus anti-cancer opportunities", 4 April 2016.
- At current market capitalisation levels, we believe that the market is discounting (only) a 2.5% probability that the RECCE® antibiotics will be commercialised. We suggest that if the RCE products successfully pass the Animal Test stage, a forecast increase in the probability to 5% would effectively double the market cap.

In summary, we believe that RCE offers exciting capital upside for speculative investors as the RECCE® antibiotic NPV is progressively derisked. RCE has an innovative patented product range, an experienced management team, and has demonstrated in recent announcements the potential to be a significant player in the global battle against both superbugs and cancer. RCE is highly active with much news flow potential. Also, it has a low-cost structure, and is fully-funded for the Animal Testing (pre-clinical) phase of the drug development programme.

### 17 August 2016

Share Price: A\$0.25

# Recommendation:

**Speculative Buy** 

Target Price: No forecast

Risk Assessment: Higher

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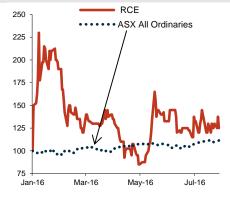
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# Recce Ltd

ASX Code	RCE
52 week range	A\$0.17-A\$0.52
Avg. Daily Turnover (shares)	64,437
Shares Outstanding (million)	68.5
M'Cap (A\$m)	17.1
Fully diluted no of shares (m)	103.5
Fully diluted M'Cap (A\$m)	25.9
Net Cash (30 June 2016)	A\$3.59m

ASX All Ordinaries 5,532

#### Relative Price Performance (base =100)



Source: IRESS, State One Stockbroking



### **Total potential value**

We estimate the total (antibiotic and anti-cancer) un-risked NPV of the RECCE® antibiotics at some US\$780m (~A\$1,040m at the current spot US\$0.75 exchange rate). See valuation methodology jn State One's report "Antibiotic plus anti-cancer opportunities", 4 April 2016.

At RCE's current (fully-diluted) market capitalisation of  $\sim$ A\$26m, we suggest that the market is attaching a 2.5% probability that the RECCE® antibiotic product will achieve commercial success.

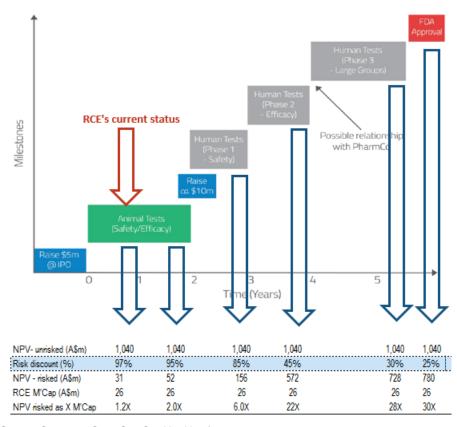
# RCE - potential total NPV (un-risked)

RECCE antibiotic - US market	180	US\$m	For antibiotic applications
RECCE antibiotic - ROW	230	US\$m	For anubious applications
RECCE antibiotic - cancer applications	370	US\$m	_
Total	780	US\$m	
AUD:USD exchange rate	0.75		_
Total	1,040	A\$m	
RCE current M*Cap	25.9	A\$m	_

Source: State One Stockbroking forecasts

The low probability reflects the early-stage nature of the product development - RECCE® antibiotics are mid-way through a program of animal tests for safety and efficacy, part of a longer-term six-year program to FDA approval. However, we believe that as the development program progresses, RCE's share price should increase significantly as the probability of commercial success increases. See graph below.

### Forecast RECCE® antibiotic development timeline



Source: Company, State One Stockbroking forecasts

Total indicative NPV valuation:

US\$780m (A\$1,040m)

At the end of Animal Tests - Safety/Efficacy, we suggest a riskadjusted valuation for RCE of ~A\$50m (i.e., 2x higher than RCE's current fully diluted m'cap)

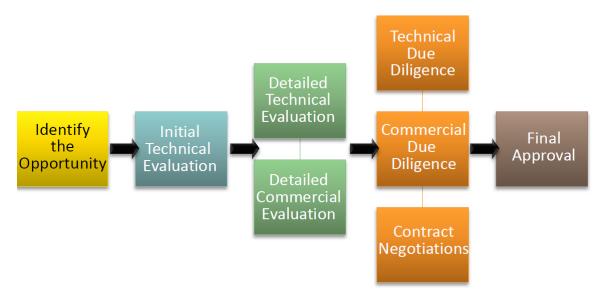
At the end of Human Tests Phase 1 - Safety, our risk-adjusted valuation for RCE is ~A\$150m (i.e., 6x RCE's current fully diluted m'cap)



#### Valuation risks

- Expenses and costs of 2016-2021 trials/development and compliance with regulations,
- High rate of failure for drug candidates (animals) proceeding through pre-clinical trials, and or failure/setbacks at any stage (Phase 1, 2,3) of the clinical trials (humans),
- Serious adverse events or safety risks could require Recce to abandon developments, and to preclude, delay, or limit approval of its products,
- Reliance on a relatively small number of key personnel,
- If Recce develops and manufactures the RECCE® antibiotic (versus selling the IP to Big Parma in exchange for a royalty), Recce will face the inherent risk of exposure to liability claims and regulatory action,
- The Company may be forced to litigate to enforce or defend its intellectual property rights,
- The Company may not be able to protect its proprietary technology in the marketplace,
- Competitors may be more successful than the Company,
- Failure to secure a Licencing/Royalty with one of the big PharmCos. The
  big players in the pharmaceutical industry have significant portfolios of
  early-stage/development prospects to evaluate; most prospects will not
  make it through the rigorous selection process. See graph below.

#### **Licensing Process at Bristol-Myers Squibb**



Source: Torreya Partners presentation, January 2014



#### **General Advice Warning**

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