

January 2018
ASX: RCE

Recce Pharmaceuticals Ltd[©]

Tackling Superbugs – RECCE® 327



Corporate summary

- Commercialising promising new class of synthetic antibiotics
- Focus is new treatments for drug resistant bacteria (superbugs)
- Based on pioneering life work of former J&J Australia head of research and executive director Dr Graham Melrose
- Oversubscribed ASX listing in 2016
- New automated manufacturing facility in Sydney, producing at levels to support proposed Phase 1 and 2 clinical trials
- Over 30 pre-clinical studies to date validate the technology
- Current focus is progressing RECCE® 327 into human clinical trials in 2018
 - scale-up of manufacturing (in USA)
 - Investigational New Drug submission (IND) to the US Food & Drug Administration (FDA)

Recce is a drug discovery and development business commercialising a new class of synthetic antibiotics to address the global health challenge of antibiotic resistant superbugs



Investment summary



Major shareholders

1.	G. & O. Melrose*	34.7%
2.	D. Foord	5.2%
3.	J. Graham*	4.1%
4.	M. Aarons	3.4%
5.	M. Dilizia*	3.3%
6.	State One	2.9%
7.	Querion Pty Ltd	1.9%
8.	F. Graham	1.3%
9.	Frank McClymont	1.2%
10.	Golden Rivers Mining Pty Ltd	1.0%

* Held by Executive Directors

Snapshot

ASX code:	RCE
Shares on issue:	87.4 million
Share price:	18.5 cents
Market cap (approx.):	\$16.12 million
Cash and deposits:	\$1.13 million
31 December 2017	
Trading range:	14.0 – 29.5 cents
52 week	
Average daily volume	114.2K
3 months	



Natural antibiotics vs synthetic antibiotics

- Overuse of antibiotics has led to antibiotic resistant bacteria in humans and animals (superbugs)
- Antibiotic resistance is now acknowledged as an urgent global health issue
- Commercial antibiotics are naturally derived – superbugs have been forming for millennia – and will continue to do so
- RECCE® 327 is a man-made synthetic compound.



Pre-formed
natural superbugs

Contain natural antibiotics



NO Pre-formed
natural superbugs

Synthetic antibiotics



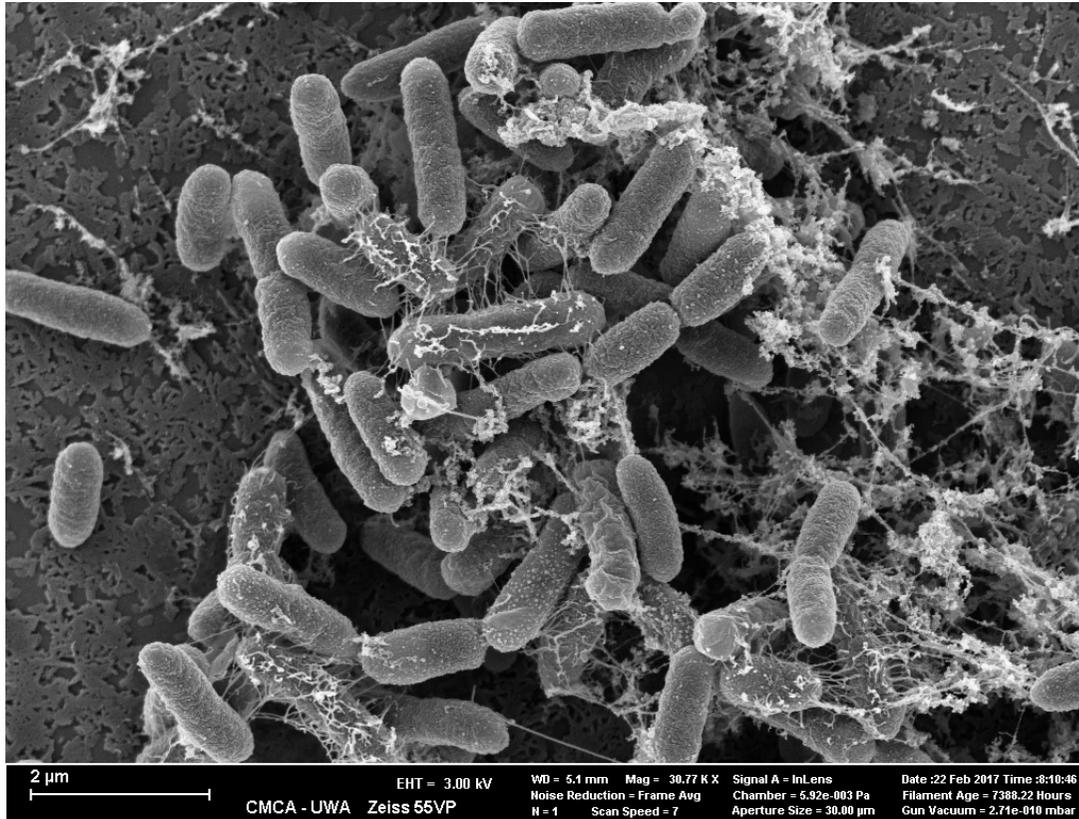
Economics of antibiotic development



- Need for new antibiotics is urgent.
- Due to economic constraints (returns vs. investment) Big pharma has largely ignored development of new antibiotics for the past decades
 - The more effective an antibiotic is, the less it is likely to be used by clinicians who want to ‘save’ it
 - Conventional antibiotics invariably suffer resistance soon after their (expensive) development
- **RECCE® antibiotics are designed to overcome antibiotic resistance – potentially breaking sales barriers/opening new opportunities**
- National governments, private groups and the United Nations (WHO) are all working to urgently address the growing threat from antibiotic resistance.
- Recce and other antibiotic developers are poised to benefit from multiple regulatory and financial incentives.
- The goal of governments and the WHO is to provide positive economic drivers for companies like Recce to innovate and expedite new treatments
- An example of this support was the FDA granting Recce Qualified Infectious Disease Product designation.



RECCE® 327 – how it works



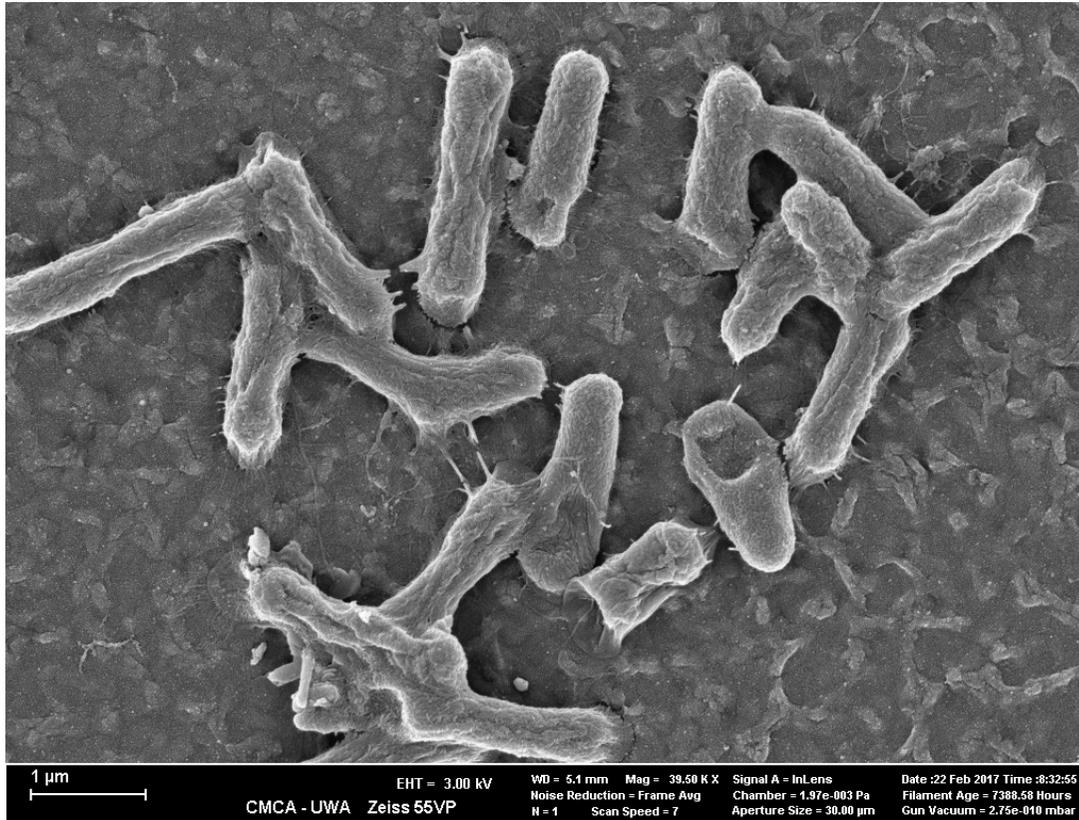
00:00 minutes

Before application of RECCE® 327, the *E.coli* bacteria cells are healthy, smooth and intact.

This is a high-definition electron microscope image generated in February 2017 by Dr Peta Clode and Lyn Kirilak of the Centre for Microscopy, Characterisation and Analysis, University of Western Australia. It was taken to demonstrate RECCE® 327's unique mechanism of action.



RECCE® 327 – how it works

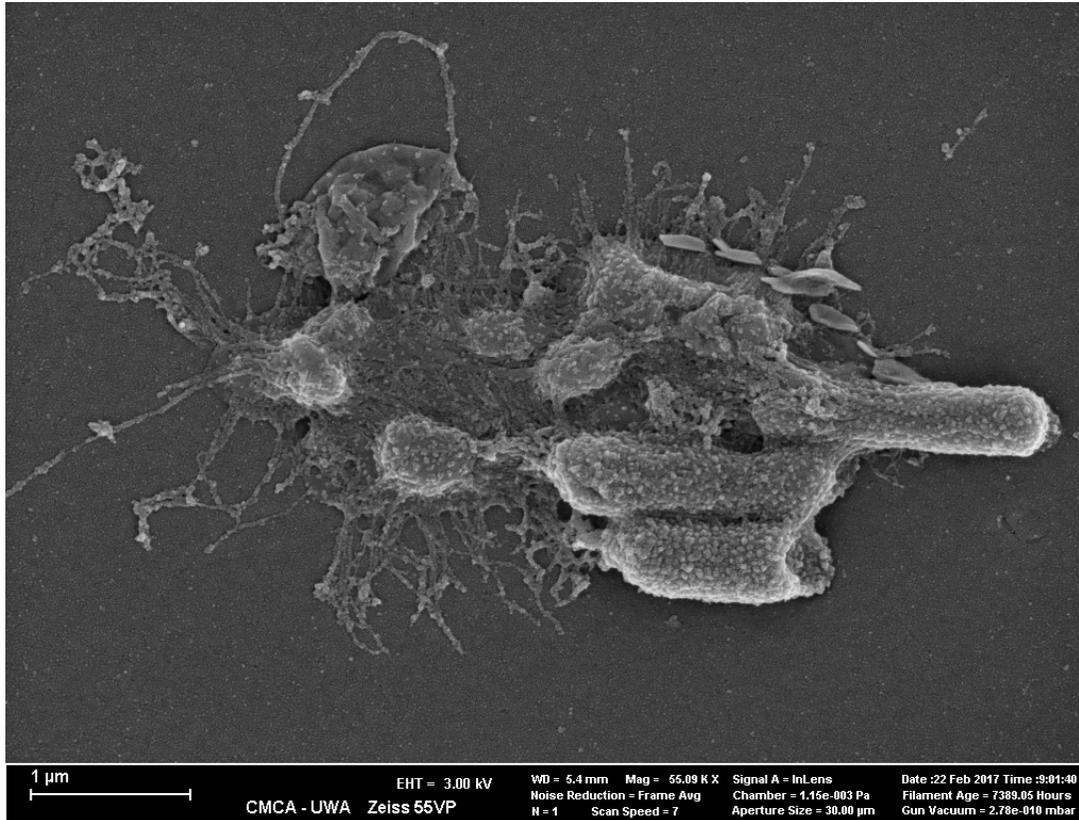


00:20 minutes

After application of RECCE® 327, the *E.coli* bacteria cell membrane begins to weaken and is disrupted.



RECCE® 327 – how it works



180 minutes

E. coli bacteria cells (10e6 cfu/ml) having their outer membrane weakened – and finally collapsing from treatment with RECCE® 327 (1000 ppm).



RECCE® 327 – Demonstrated efficacy and safety



Efficacy

- Multiple tests demonstrate efficacy against Staph (Gr +ve) and E.coli (Gr –ve), including superbug forms
- Rate and MIC/MKC data demonstrate high potency and broad spectrum activity against range of bacteria
- *In vivo* (mice) study against Influenza virus.

Safety

- Multiple studies of toxicity completed in small and large animals
- Multiple tests of mutagenicity (cancer) are clear

What does this all mean? Over 30 pre-clinical studies to date indicate RECCE® 327:

- Does not cause healthy cells to mutate (to cause cancer)
- Destroys Gram positive and Gram negative bacteria - broad spectrum
- Acts against bacteria in both normal and mutated superbug forms – with the same ease
- Contains a patented polymeric structure, intentionally designed to overcome the traditional challenges of bacterial mutation/resistance (superbugs)
- Is suited to administration against sepsis by intra-venous drip
- Has a wide and safe therapeutic dosing window.



RECCE® 327 – Clinical and commercial advantages



Clinical

- Broad spectrum activity with no loss of efficacy - any bacteria in the blood is bad - RECCE® 327 kills regardless of type or mutation
- Same dose for pathogenic bacteria, in natural or superbug forms – don't need to determine bacterial count/type before treatment
- Active against superbug forms of bacteria – [previously resistant, now treatable](#)
- Current clinical focus is [Sepsis, S. aureus \(Staph\) and Escherichia coli \(E. coli\)](#)
- First drug designed specifically for the treatment of sepsis – over 30 million cases/annum

Commercial

- FDA has awarded RECCE® 327 Qualified Infectious Disease Product designation (QIDP) status – Fast Track/10 years market exclusivity (post approval)
- Significant economies of production (time and cost)
- Eligible for international concessions – legal status approved under *US Generating Antibiotic Incentives Now (GAIN)* act
- Not a single product company – technology offering multiple paths to profitability



What is Qualified Infectious Disease Product designation



Qualified Infectious Disease Product designation (QIDP) is awarded if FDA considers the drug to treat “*serious or life-threatening infections, including those caused by an antibacterial or antifungal resistant pathogen.*”

- Legal status awarded under *US Generating Antibiotic Incentives Now (GAIN) Act*
- Labeled for Fast Track designation - Speed the FDA’ s review process
- 10 years market exclusivity, starting from the date of New Drug Application approval if RECCE® 327 completes the necessary clinical trials and is approved by the FDA
- QIDP designated drugs to treat serious or life-threatening conditions and fill an unmet medical need, are labeled for expedited review in order to facilitate their development.

In its letter to Recce Pharmaceuticals Ltd, the FDA wrote:

“We have reviewed your request and conclude that it meets the criteria for QIDP designation for the requested indication. Therefore, we are designating your RECCE 327 product for intravenous use as a QIDP for the following indication: Bacteremia caused by Escherichia coli and Staphylococcus aureus.”



Sepsis – our first clinical target

Why target Sepsis (blood poisoning)?

- Sepsis affects an estimated 30 million people worldwide every year – 1/3 of cases are fatal
- In the developing world sepsis accounts for 60-80% of lost lives per year
- In the US, + 750,000 cases of severe sepsis are recorded every year
- Sepsis is the single most expensive condition treated in US hospitals
- Sepsis kills more people than breast cancer, colon cancer and HIV Aids combined

- Pharmaco-economic burden >US\$20 billion in annual hospital costs in US alone
- The annual rate of sepsis is increasing in developed countries at a rate of 8-13%
- **Currently no drug therapies specifically for the treatment of sepsis**

Above statistics available from a number of sources, primarily [Global Sepsis Alliance](#) and [National Institute of General Medical Sciences](#)



Objectives for next 12 months

Regulatory

- Continue regulatory initiatives with the FDA, aimed at approval of RECCE[®] 327
- With world leading FDA consultants (helped 95% of the 200 top-selling biopharmaceuticals), design and recruit a small number of participants for Phase 1 clinical trials of RECCE[®] 327.
- Enter into clinical trials of RECCE[®] 327
- Present initial Phase 1 data to US FDA

Operational

- Launch 'Recce Pharmaceuticals' - broaden applications of technology – synergistic advantages
- Expand existing wealth in intellectual properties by securing additional patents
- Build international interest with leading life sciences communications group Instinctif Partners
- Begin US manufacturing opportunities – commercial scale



Investment summary



- Pipeline of new synthetic antibiotics based on powerful validated proprietary technology
- Initial focus on treating drug resistant sepsis (blood poisoning) - RECCE® 327
- A high unmet clinical need supported by favorable legislative and financial incentives
- Lead candidate with significant pre-clinical validation demonstrating safety and efficacy
- Experienced Board and management with a track record of delivering commercial outcomes
- Currently in discussions with the US FDA, having been granted QIDP designation
- Focused on creating value by continuing to meet milestones



Thank you

Contact

James Graham
Executive Director

T: + 61 2 8075 4585

M: +61 431 978 682

E: james.graham@recce.com.au

