



James Graham Executive Director

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About Recce Pharmaceuticals Ltd



- Founded in 2008
- Publicly listed on ASX 2016 (ASX:RCE)
- Whole new class of antibiotic
- ▶ RECCE[®] 327 broad spectrum antibiotic for sepsis
- Qualified Infectious Disease Product (QIDP) designation RECCE[®] 327 labelled under GAIN Act for:
 - 10 years market exclusivity (post approval)
 - Fast track (life of regulatory process)
- Patented manufacturing to Phase I & II volumes
- In discussion with US Food & Drug Administration

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.



Capital structure



Major shareholders 31 March 2018

1. G. & O. Melrose*	35.0%
2. Foord Asset Management	5.2%
3. J. Graham*	4.1%
4. M. Dilizia*	3.3%
5. State One Equities	2.9%



* Held by Executive Directors



Snapshot

ASX code	RCE
Shares on issue	89.34 million
Share price	20 cents
Market cap (approx.)	\$17.8 million
Cash and deposits 31 Dec 2017	\$1.13 million
Trading range ^{52 week}	13.5-26.0 cents
Average daily volume 3 months	110.7K

Tackling Superbugs – RECCE® 327 (Video)







Sepsis – it's a big problem!



- Sepsis is a life threatening inflammatory response to infection that has spread in the body
- Leading cause of death in intensive care units and top 10 cause of mortality worldwide
- Two per cent of hospitalisations are for sepsis but they make up 17% of in hospital deaths
- Care is improving but the incidence of severe sepsis is increasing rapidly
- Most expensive condition to treat double the average cost per stay across all other conditions
- Currently no drug therapies specifically for the treatment of sepsis
- Desperate and unmet medical need for new safe and efficacious products





Natural antibiotics vs synthetic antibiotics



- Overuse of antibiotics has led to antibiotic resistant bacteria in humans and animals (superbugs)
- Antibiotic resistance is widely 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 – no superbugs to it and detailed experimentation indicates it <u>will never form superbugs</u> thanks to its unique mechanism of action.





Independent study* example treating sepsis



- Three groups of 10 mice were each infected with MRSA (*S.aureus* superbug)
- All ten mice treated with RECCE[®] antibiotic survived
- Nine mice treated with current antibiotic (Oxacillin) survived
- Four mice that had no treatment at all, survived

Number of Mice that survived Sepsis from *S. aureus* (superbug)



* Results from an independent laboratory in USA

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RECCE® 327 mechanism of action in practice



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00:00 minutes

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

RECCE® 327 mechanism of action in practice



20 minutes

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





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RECCE® 327 mechanism of action in practice





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

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



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What is Qualified Infectious Disease Product?



- 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

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



RECCE® 327 – clinical and commercial advantages

Clinical – safety and efficacy

- Broad spectrum activity
- Same dose for pathogenic bacteria, in natural or superbug forms
- Active against superbug forms of bacteria
- Numerous studies to date indicate the safety of RECCE[®] 327
- Focus is Sepsis, S. aureus (Staph) and Escherichia coli (E. coli)
- First drug designed specifically for the treatment of sepsis

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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
- Designed as a multiple product company
 - technology offering multiple paths to profitability



Example for representative purposes only



Board and management structure



Dr Graham Melrose - Executive Chairman

BSc (Hons), PhD (UWA), MBA (Macq), FRACI, C Chem, FAICD Founder and inventor. Former Executive Director and Chief Research at Johnson & Johnson (Aust) Pty Ltd in Sydney, with global responsibilities, particularly in Asia-Pacific

Michele Dilizia - Executive Director

BSc (Med Sci), Grad Dip Bus (Mkting), BA (Journ), GAICD, MASM Co-inventor and qualified medical scientist; specialisation in medical microbiology and regulatory affairs

James Graham – Executive Director

BCom (Entrepreneurship), GAICD

Extensive experience in marketing, business development and commercialisation of early stage technologies with global potential

Dr John Prendergast - Non-Executive Director

BSc (Hons), MSc (UNSW), PhD (UNSW), CSS (HU)

US based, current Chairman and Co-founder of Palatin Technologies, Inc. (NYSE: PTN) and Lead Director of Heat Biologics, Inc. (NASDAQ: HTBX) – extensive experience in the international commercialisation of pharmaceutical technologies

Alistair McKeough (McKeough & Whittens) – outsourced Company Secretary

Alistair is a qualified lawyer and Principal/Managing Director of McKeough & Whittens, Alistair has broad experience as a commercial litigator and Company Secretary to ASX Listed companies

Justin Reynolds (Pitcher Partners Sydney) – outsourced CFO

Justin is a qualified accountant and Partner of Pitcher Partners Sydney, Justin has broad experience covering all areas of accounting, taxation and assurance. Particularly, Justin's areas of expertise are business services and outsourced accounting

Arthur Kollaras – Principal Engineer

BSc Beng (Chem), PhilEng (Enviro)

Highly qualified in chemical engineering and microbiology, has significant experience taking a new technology concept to pilot plant and full scale FDA standards and production internationally

Dr Justin Ward - Principal Quality Chemist

BSc (Chem), PhD (Chem), MRACI, CChem

A quality control expert who has worked with leading pharmaceutical companies, he is bringing Recce's research and development, and manufacturing up to US FDA requirements



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Economics of antibiotic development

- Due to economic constraints big pharma has largely ignored development of new antibiotics for the past decades
 - The more effective an antibiotic is, the less likely it is 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

Example: Unique mechanism of action indicates RECCE[®] antibiotics WILL NOT become susceptible to bacterial mutation (superbugs) no matter repeated bacterial exposure (use). Clinicians could quickly administer, knowing it WILL work (Grampositive, Gram-negative or superbugs), stopping the infection - restricted use may be a thing of the past!



Global market interest in antibiotic resistant treatments – M&A activity



Date	Company	Acquired/merger/ acquisiton by	Deal value (US\$)	Phase acquired	Detail
Dec-14	Cubist	Merck	<u>\$8.4bn</u>	Ph 3	Antibiotics - one marketed - Cubicin for G-pos <u>\$625m</u> (revenue in 2010, over \$1bn in 2013) – mostly MRSA
Aug-16	Astra Zeneca (antibiotics)	Pfizer Inc	<u>\$1.5bn</u>	Ph 2-NDA	Late-stage small molecule antibiotics business – most markets outside the US only
Jan-15	Meiji Seika Pharma & Fedora	Roche	<u>Up to \$750m</u>	Ph 1	Beta-lactamase inhibitor (ex. Japan)
Oct-17	Warp Drive Bio	Roche	<u>Up to \$387m</u>	Device	Potential natural antibiotic identification technology
Dec-17	Summit Therapeutics	Eurofarma	<u>Up to \$27m</u>	Ph 2	Clostridium difficile infection (Latin America only)
May-16	Vertex Pharma	Spero Therapeutics	Not disclosed	Ph 1	Bacterial infections
Jan-18	Prokaryotics	Merck	Not disclosed	Preclinical	Bacterial cell envelope enzymes
Mar-18	Redx Pharma	Deinove	Not disclosed	Preclinical	Gram-negative bacteria



Manufacturing and production



- Wholly owned automated manufacturing facility in Sydney's Macquarie Park
- Raw materials plentiful and CHEAP few \$/kilogram
- Automated manufacture process taking around 1¼ hours
- ► No expensive waste 99.9% product yield
- Currently producing in volumes to support planned Phase I and Phase II clinical trials
- Facility built to pharmaceutical specification will grow



Principal Engineer Arthur Kollaras & Executive Chairman/Chief Research Officer Dr Graham Melrose assess finished product



RECCE® antibiotics – a technology



Recce's technology enjoys the added opportunity of multiple markets and product categories.



Current RECCE® 327 development program



Estimated timelines/indications are subject to changes in development plans and regulatory requirements/clarifications

NDA - New Drug Application

MAA - Marketing Authorisation Application



China

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Patents and trademarks

Filed	Patent Family 1 <u>Granted</u>	Expiry	Patent Family 2 & 3	Expiry	Trademarks registered	Unique and highly economical manufacturing process
Australia	\checkmark	2028	Pending	2034	\checkmark	
USA	\checkmark	2029	Pending	2034	√	Patent Family 2 – pending Applications (Multi drug delivery)
Europe	\checkmark	2028	Pending	2034	\checkmark	
Germany	\checkmark	2028	Pending	2034	-	
Spain	\checkmark	2028	Pending	2034	-	
France	\checkmark	2029	Pending	2034	-	Patent Family 3 – pending
United Kingdom	\checkmark	2028	Pending	2034	-	Anti-viral uses
Italy	\checkmark	2028	Pending	2034	-	
Sweden	\checkmark	2028	Pending	2034	-	Trademarks
Japan	\checkmark	2028	Pending	2034	\checkmark	RECCE [®] for use on
China	\checkmark	2028	Pending	2034	-	pharmaceutical products and services

Patent portfolio covers all key geographies, manufacturing and modes of use

Pharmaceuticals

Patent Family 1 – granted

RECCE® 327 overview



Advantages unique to RECCE® antibiotics

- Avoids time-consuming diagnosis/guess work (patient survival decreases by 6% every hour left un-treated)
- Active against all tested superbug forms of bacteria
- Does not lose efficacy with repeated use
- New synthetic with NO superbugs against it
- New class of antibiotic
- First drug designed specifically for the treatment of sepsis

Corporate advantages unique to Recce

- Extraordinary economy of production in only a few steps
- Production method very easily varied to produce different antibiotics for specific purposes
- Many variants to the Recce technology opens the opportunities and securities of alternative uses, e.g. *H. Pylori*, *E. coli*, virus, veterinary and antiseptic markets



Investment summary





management and Board

Thank you

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WHO – an urgent need for new antibiotics



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Global priority list of antibiotic – resistant bacteria to guide research, discovery and development of new antibiotics

- WHO published a global priority pathogens list of antibiotic-resistant bacteria
- Its purpose was to identify the most important resistant bacteria at a global level
- The list includes 12 pathogens prioritized in three categories Critical, High and Medium

- 1. Active in vitro against Recce's own superbug of this bacterium
- 2. Active in vivo against a member of this family CRE E. coli
- 3. Active in vitro against a very closely related species, Enterococcus faecalis, Vancomycin resistant
- 4. Active both in vitro and in vivo against MRSA, Methicillin-resistant Staphyloccocus aureus
- 5. Active both in vitro and in vivo against three strains (2 of which were superbugs)
- Active in vitro against the normal bacterium (superbug form unavailable)
 Active in vitro against related superbug Klebsiella pneumoniae



PRIORITY 1: CRITICAL	RECCE [®] 327
Pseudomonas aeruginosa, carbapenem-resistant	✓ 1
<i>Enterobacteriaceae,</i> carbapenem-resistant, ESBL-producing	√ 2
Acinetobacter baumannii, carbapenem-resistant	Not Tested
PRIORITY 2: HIGH	
<i>Enterococcus faecium</i> , vancomycin-resistant	√ 3
Staphylococcus aureus, methicillin-resistant, vancomycin-intermediate and resistant	√ 4
Helicobacter pylori, clarithromycin-resistant	✓ 5
Neisseria gonorrhoeae, cephalosporin-resistant, fluoroquinolone-resistant	√ 6
Campylobacter spp., fluoroquinolone-resistant	Not Tested
Salmonellae, fluoroquinolone-resistant	Not Tested
PRIORITY 3: MEDIUM	
Streptococcus pneumoniae, penicillin-non- susceptible	✓ 7
Haemophilus influenzae, ampicillin-resistant	Not Tested
Shigella spp., fluoroquinolone-resistant	Not Tested

RECCE® 327 – how it works (in more detail)

- RECCE[®] antibiotics, attracted by protein in a bacteria's outer membrane, non-specifically attach through hydrophobic interaction
- Weakening the outer cell wall, internal pressure causes the bacteria to burst and lose viability
- Outer protein can mutate as much as it likes (superbug) -RECCE[®] antibiotic will still kill it

RECCE® 327 – safety and efficacy (detail)

Efficacy

- Performs as a broad spectrum antibiotic
- Acts against bacteria in both normal and mutated superbug forms
- Multiple tests demonstrate efficacy against Grampositive S.aureus (Staph) including superbug forms
- Multiple tests demonstrate efficacy against Gramnegative *E.coli* including superbug forms
- Rate and MIC/MKC data demonstrates potency and broad spectrum activity against range of bacteria
- Contains a patented polymeric structure, intentionally designed to overcome the traditional challenges of bacterial mutation/resistance
- In-vivo (mice) study against influenza virus

► Safety

- Multiple studies of toxicity in small and large animals
- Multiple tests of mutagenicity (cancer) are clear
- Numerous studies to date indicate the safety of RECCE[®] 327
- Is suited to administration against sepsis by intra-venous drip
- Indicates a safe therapeutic dosing window

