

ASX Announcement

Recce Meets Antibiotic Leaders to Explore Commercial and Clinical Opportunities

Sydney, Australia, 25 October 2018: Recce Pharmaceuticals Ltd (ASX: RCE), the company developing a new class of synthetic antibiotics, today announced it will be represented at the World Anti-Microbial Resistance Congress in Washington D.C., 25 - 26 October 2018.

The conference features 150 speakers from 20 countries and is a leading international forum for researchers, investors, businesses and governments working to address antibiotic resistance.

Recce Executive Chairman Dr Graham Melrose said, "There is growing international interest in our new class of broad-spectrum synthetic antibiotic technology. With a range of meetings secured, this event allows us to efficiently engage with potential business and clinical partners to discuss commercial and clinical opportunities as we advance towards the start of human clinical trials".

Recce's lead compound, RECCE® 327, is being developed as a new class of antibiotic, for the treatment of blood infections and sepsis derived from *E. coli* and *S. aureus* bacteria – including their superbug forms. It was awarded Qualified Infectious Disease Product (QIDP) designation in late-2017, as part of the US Generating Antibiotic Incentives Now (GAIN) Act, labelling it for Fast Track Designation, plus 10 years of market exclusivity post approval.

In 2018, the Company successfully secured almost half of its R&D budget from Australian Government funding.

About Recce Pharmaceuticals Ltd

Recce Pharmaceuticals Ltd (ASX: RCE) is pioneering the development and commercialisation of a new class of synthetic antibiotics with broad spectrum activity designed to address the urgent global health problem of antibiotic resistant superbugs. Its patented lead candidate known as RECCE® 327 has been developed for the treatment of blood infections and sepsis derived from *E. coli* and *S. aureus* bacteria – including their superbug forms. Pre-clinical testing in laboratories and animal models, in Australia and overseas has demonstrated positive results. Recce has a manufacturing



ASX: RCE

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facility in Australia and is developing clinical research partners in the USA. The Company has developed an automated process to manufacture its lead compound ahead of first-in-human clinical trials.

For further information please visit www.recce.com.au or contact:

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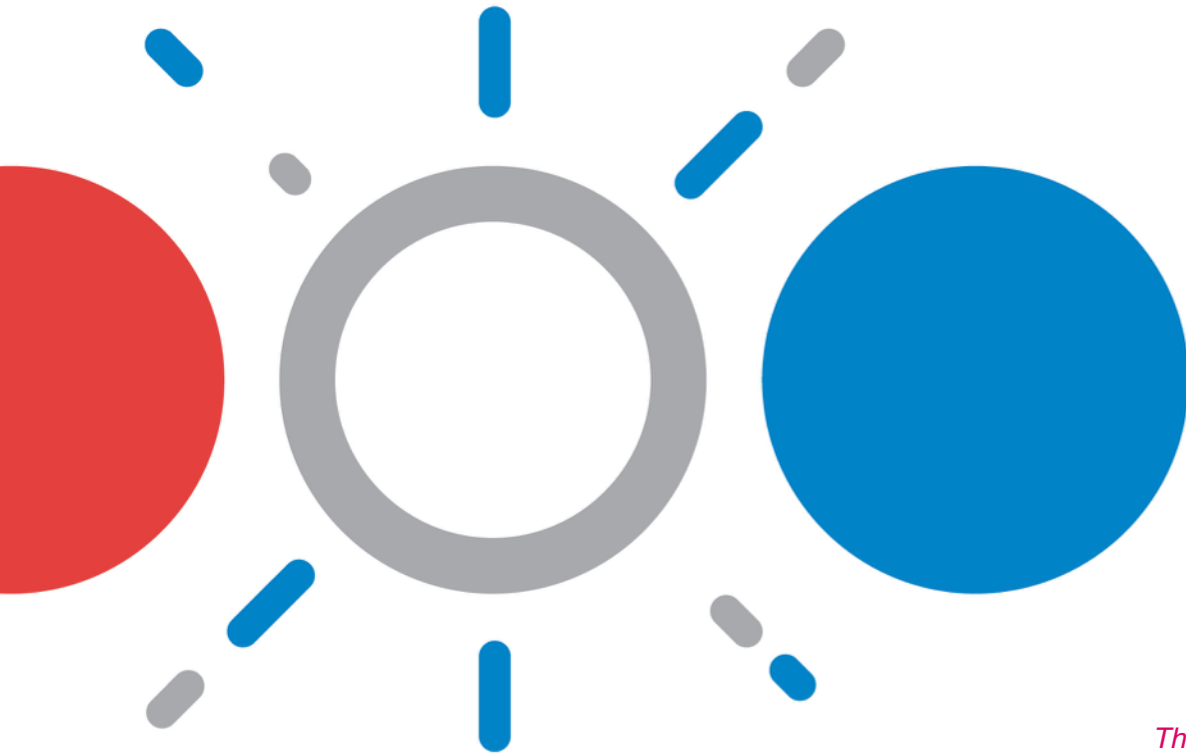
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**World Anti-Microbial
Resistance Congress**

2018

The leading conference on anti-microbial resistance

October 2018

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About Recce Pharmaceuticals Ltd

- ▶ Founded in 2008
- ▶ Publicly listed on ASX 2016 (ASX:RCE)
- ▶ Whole new class of antibiotic that kills bacteria including its superbug form even with continued use
- ▶ RECCE® 327 – broad spectrum antibiotic; lead indication is for sepsis - #1 most expensive condition
- ▶ 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 producing to Phase I & II volumes



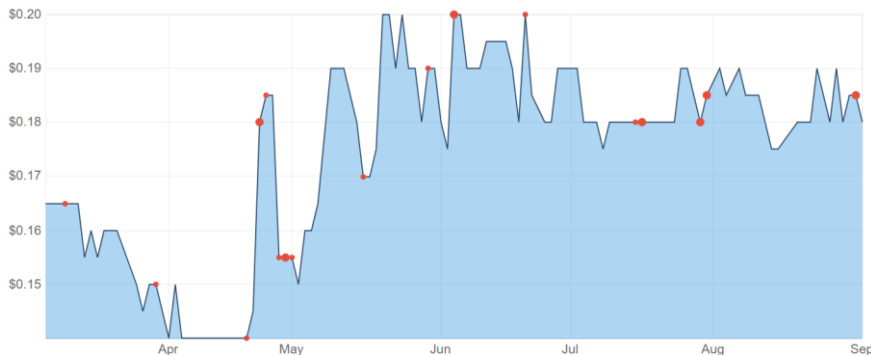
Recce is a drug discovery and development business, commercialising a new class of synthetic antibiotics to address the global health challenge of antibiotic resistant superbugs.

Recce Pharmaceuticals Ltd - Capital structure

Major shareholders 30 September 2018

1. G. & O. Melrose*	35.0%
2. Foord Asset Management	4.6%
3. J. Graham*	4.0%
4. M. Dilizia*	3.2%
5. State One Equities	2.8%

ASX:RCE 6 months



* Held by Executive Directors



Snapshot

ASX code	RCE
Shares on issue	89.34 million
Share price	AUD 19 cents
Market Cap (approx.)	USD \$12.1 million
Cash and deposits 30 June 2018	USD \$0.5 million
Trading range 52 week	AUD 14-26.0 cents
Average daily volume 3 months	84.4K

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 new class of broad-spectrum antibiotic
 - Entirely man-made and designed with purpose – not reliant on what's found in nature.
 - **Unique mechanism of action** – many 'Active-sites', as opposed to the traditional (natural) antibiotics 'few'.
 - Universal mechanism of action - detailed experimentation demonstrates it does not succumb to superbugs.



Pre-formed
natural superbugs

Contain natural antibiotics



NO Pre-formed
natural superbugs

Synthetic antibiotics

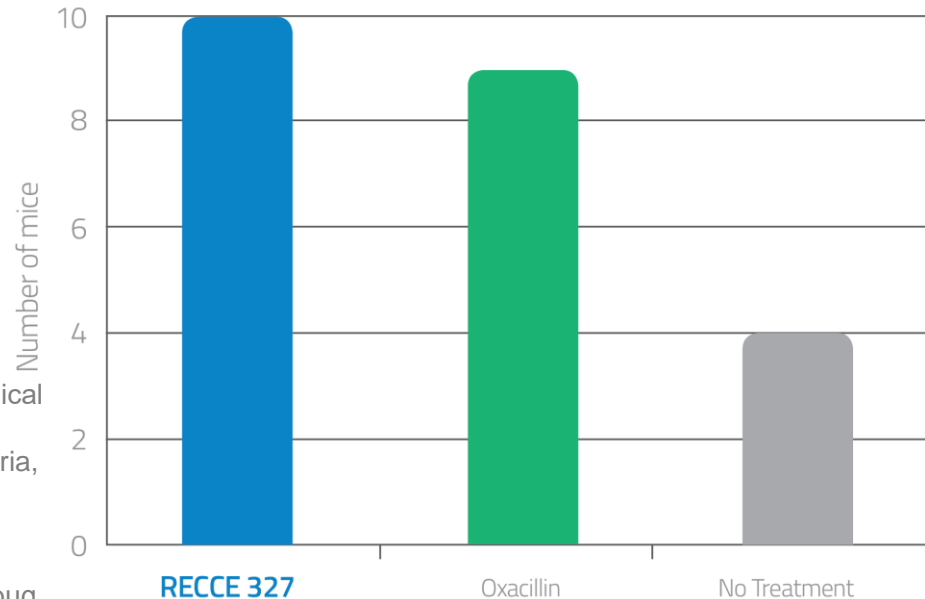
RECCE® Antibiotics – Curative study*

- ▶ 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

Note: Oxacillin was chosen for its known activity against MRSA. It is however a 'narrow-spectrum' antibiotic. In a clinical context, where diagnostics cannot immediately determine bacterial type, use in combatting any number of other bacteria, may likely see a less favorable patient outcome...

RECCE® 327, with its proven 'broad-spectrum' activity, has shown strength against a range of bacteria including superbug forms, delivering rapid kill of deadly germs.

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

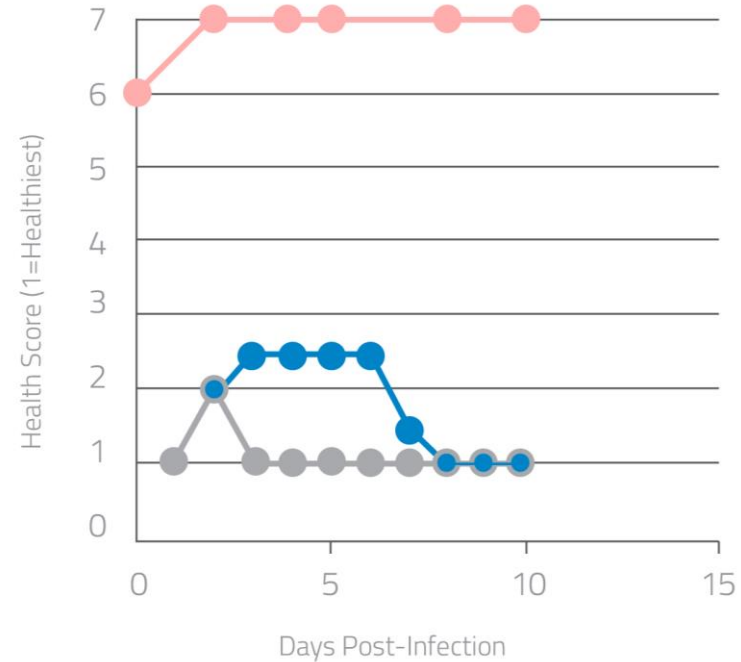


RECCE® Antibiotics – Preventative study*

Health scores in mice were maintained:

- ▶ Blue points represent infected mice that received treatment with RECCE® 327
- ▶ Grey points represent no infection
- ▶ Orange points represent infection without treatment (industry recognised data for MRSA infection)
- ▶ One group of 10 mice was infected with *S. aureus*
- ▶ Both groups of 10 mice were treated with RECCE® 327 at 132 mg/Kg
- ▶ RECCE® antibiotic in-vivo is at this dose
 - Both antimicrobial-active against *S. aureus* superbug and non-toxic.

Sepsis in Mice
from *S. aureus* (superbug)



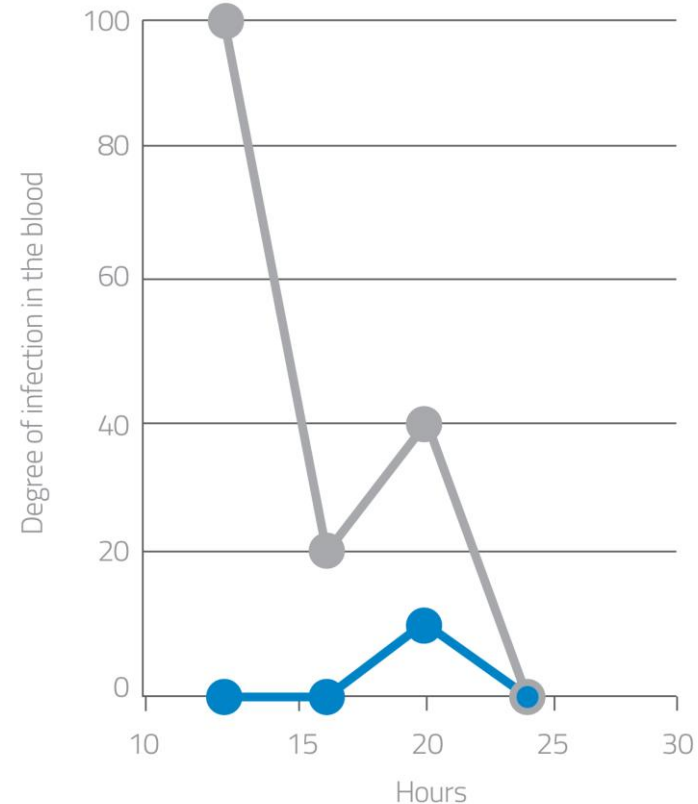
RECCE® Antibiotics – Preventative study*

Health scores in mice were maintained:

- ▶ Blue points represent treatment
- ▶ Grey points represent not treated
- ▶ Both groups of mice infected with *S. pyogenes*
 - Only one group treated with RECCE® antibiotics
- ▶ **RECCE® antibiotic in-vivo is antimicrobial active**
- ▶ After the 12 hour-point, *S. pyogenes* germ was cleared naturally from the blood by RECCE® antibiotics
- ▶ No treated animals displayed any significant adverse signs

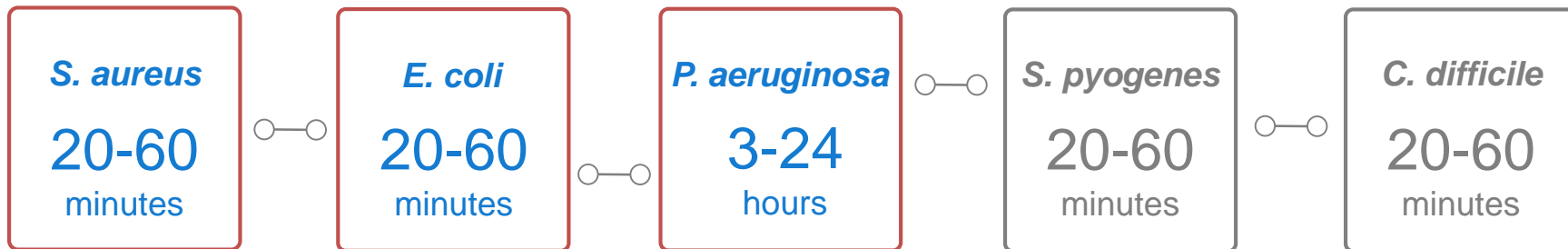
* Results from an independent laboratory in USA

Sepsis in mice from *S. pyogenes*

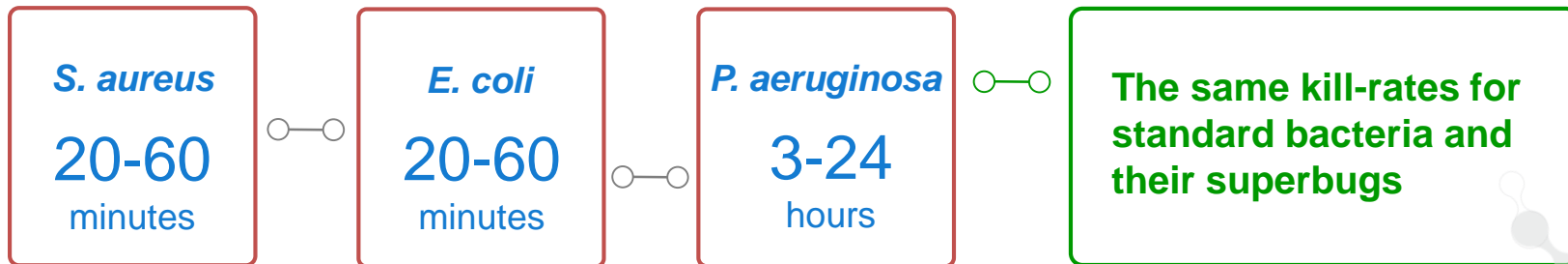


RECCE[®] antibiotics kill at practical speeds

Rates of kill of standard bacteria



Rates of kill of Superbugs



RECCE® antibiotics do not Fail¹

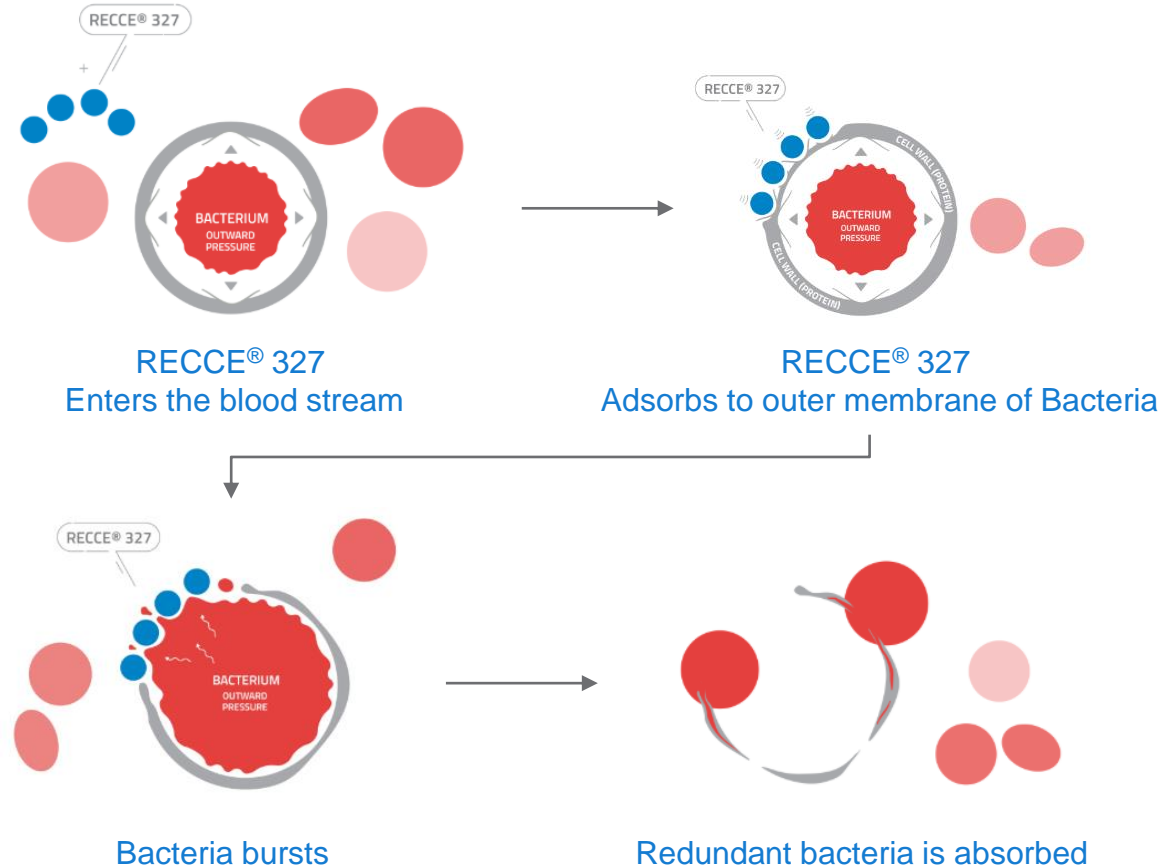
Number of repetitive uses before displaying loss of antibiotic activity



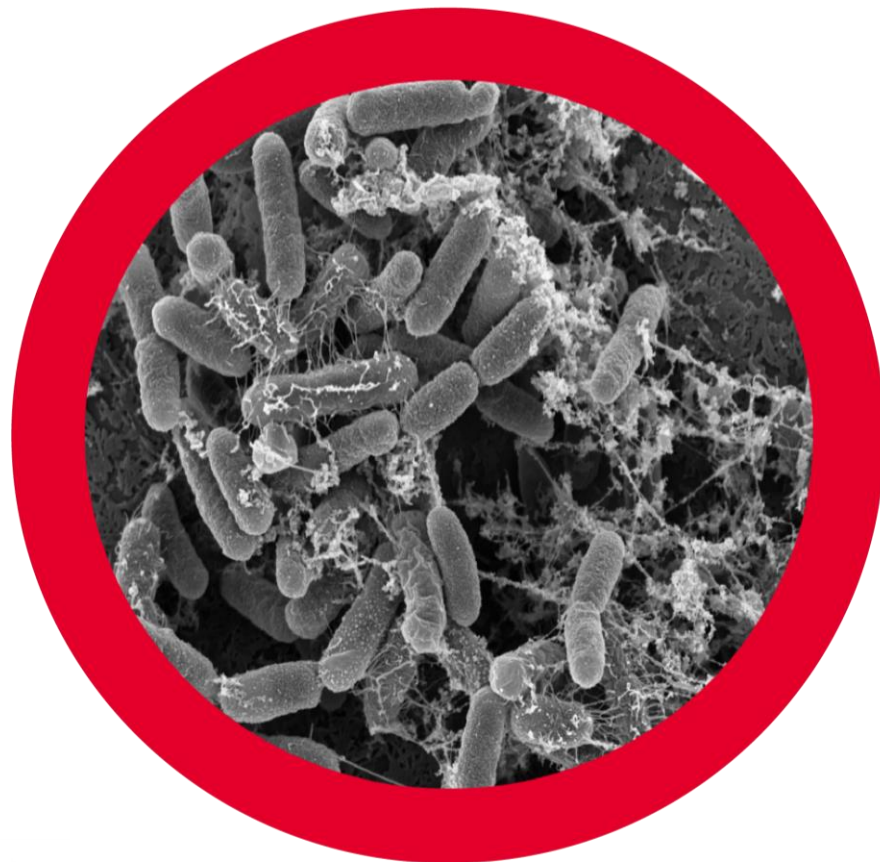
¹After repetitive use, the commercial antibiotic loses activity; >25 repeats **RECCE® antibiotic DOES NOT**

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!



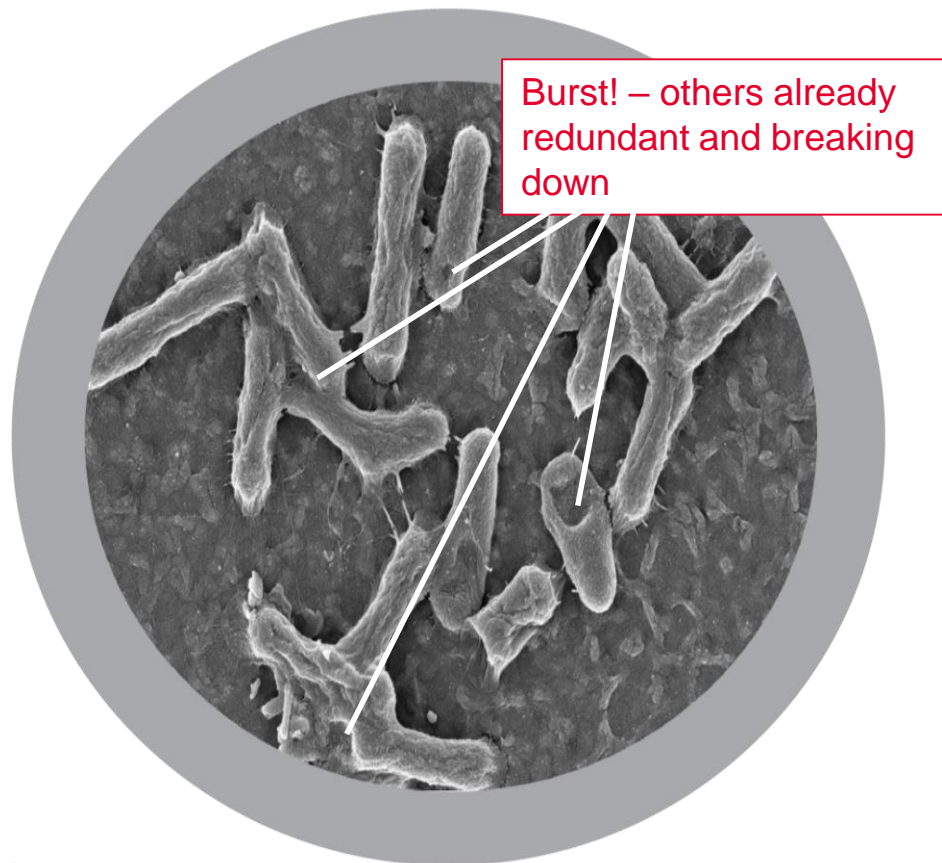
RECCE® 327 mechanism of action in practice



00:00 minutes

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

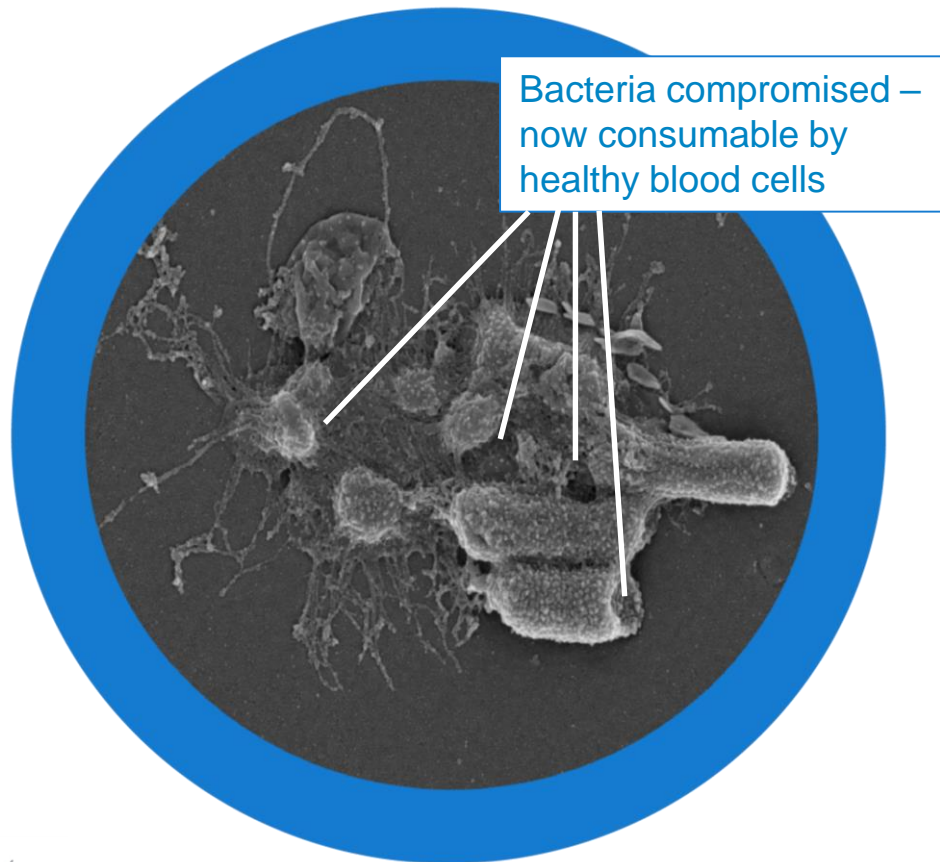
RECCE® 327 mechanism of action in practice



20 minutes

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

RECCE® 327 mechanism of action in practice



180 minutes

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

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 Gram-positive and Gram-negative *S.aureus* and *E.coli* including superbug forms
- Rate and MIC/MKC data demonstrates potency and broad spectrum activity against a 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



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.*”



Patents and trademarks

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

Filed	Patent Family 1 <u>Granted</u>	Expiry	Patent Family 2/3	Expiry	Trademarks registered
Australia	✓	2028	✓	2035	✓
USA	✓	2029	Pending	2035	✓
Europe	✓	2028	Pending	2035	✓
Germany	✓	2028	Pending	2035	-
Spain	✓	2028	Pending	2035	-
France	✓	2029	Pending	2035	-
United Kingdom	✓	2028	Pending	2035	-
Italy	✓	2028	Pending	2035	-
Sweden	✓	2028	Pending	2035	-
Japan	✓	2028	Pending	2035	✓
China	✓	2028	Pending	2035	✓

Patent Family 1 – granted

Unique and highly economical manufacturing process

Patent Family 2 – pending

Applications (Multi-drug delivery)

Patent Family 3 – pending

Anti-viral uses

Trademarks

RECCE® for use on pharmaceutical products and services

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



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

Board and management structure

Dr Graham Melrose – President & CRO

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 – Vice President

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 – Vice President

BCom (Entrepreneurship), GAICD

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

Dr John Prendergast – Non-Executive Vice President

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 – Company Secretary (Outsourced - Whittens & McKeough)

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 – CFO (Outsourced - Pitcher Partners Sydney)

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), MIEAust, MISPE

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

Economics of antibiotic development

A challenged business model – the antibiotic industry:

- ▶ Traditionally the more effective an antibiotic, the less likely it is to be used by clinicians who want to 'save it'. Less use – less sales...
- ▶ Conventional antibiotics commonly suffer resistance quickly; investment in 'new' drug candidates a risk ROI
- ▶ Pharmco's cutting antibiotic R&D – yet market need has never been greater

How might one 'unlock' the anti-infectives industry?

- ▶ A new class of antibiotics – having a unique mechanism of action that DOES NOT lose effectiveness with 'bacterial mutation' – superbugs – even with repeated use
- ▶ Broad spectrum capabilities against deadly bacteria, Gr +/- and superbugs
- ▶ A drug that can be administered quickly, without impractical diagnostic delays, where clinical 'guess-work' could be a thing of the past!

Indications suggest RECCE® 327 may just be this needed change



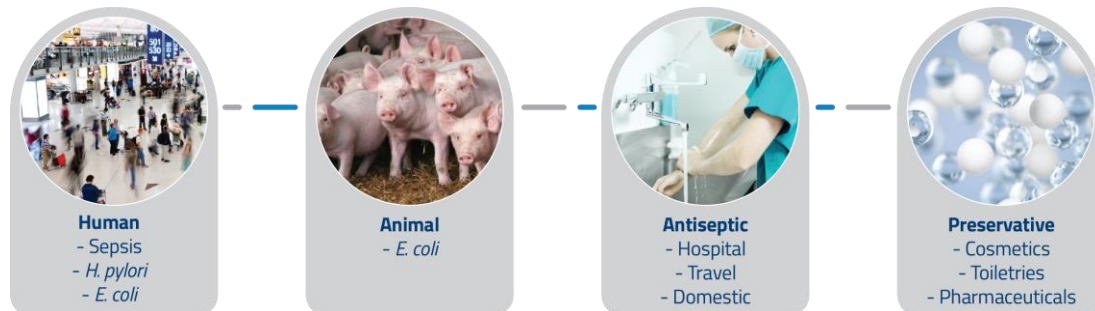
US Legislative Support of Antibiotic Development

- ▶ US *Right-to-Try Act* passed in May/June 2018
- ▶ **Designed to give US patients with life threatening diseases, immediate and direct access to potentially lifesaving drugs** - that have completed Phase I clinical trials
- ▶ New legislation mitigates possibility of weeks of procedural delay - Previous legislation termed Compassionate Use
- ▶ **Potentially resulting in improved patient outcomes**
 - With reduced risk to those providing them
 - Potential to build earlier ‘direct’ distribution – diluting late-stage pharma market access model
- ▶ Further evidence of evolving regulatory environment in the US - Largest antibiotic market in the world
- ▶ Potential aimed at **expediting new drugs with lifesaving potential**
- ▶ Legislation does not affect Company’s business at present



RECCE® Antibiotics – 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 change in development plans and regulatory requirements/clarifications

FIH - First-in-human

*Testing for RECCE® antibiotic Safety and Efficacy

**Data submissions to regulators for permission to market

Investment summary



Qualified Infectious Disease
Product Designation (QIDP)



Generating Antibiotics Incentive
Now (GAIN) Act approved



Proprietary technology as a
new class of antibiotics



Lead compound addressing
the most expensive condition
faced by hospitals worldwide



Early commercialisation
potential



Initial focus on sepsis-
potentially the first treatment
for sepsis



Favourable legislative and
financial landscape



Experienced commercial
management and board



Creating value by meeting
key milestones



Established manufacturing
(volumes suitable for Ph I/II)

Thank you

James Graham
Executive Director

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