

ASX Announcement

Investor Presentation – April 2019

Sydney, Australia, 10 April 2019: Recce Pharmaceuticals Ltd (ASX: RCE) (**Company**) provides the **attached** Investor Presentation to the market, which includes the following key highlights:

- An overview of the Company and its lead compound, RECCE[®] 327;
- An outline of the TGA Special Access Scheme regime; and
- An overview of how RECCE[®] 327 is manufactured.

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 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.

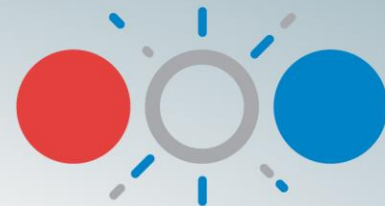


ASX: RCE

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Recce

Pharmaceuticals

James Graham - Executive Director

Non-Deal Roadshow Singapore & Hong Kong

Healthcare Investor Day

Spark⁺ April 2019

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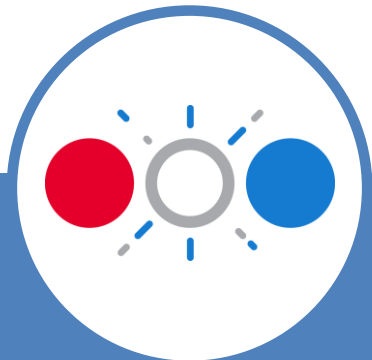
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About Recce Pharmaceuticals Ltd

Recce Pharmaceuticals is commercialising a New Class of Broad Spectrum antibiotics to address the global health issue of antibiotic resistant superbugs.



Listed on ASX 2016
(ASX:RCE)



New Class of Broad Spectrum antibiotics that kill Gram + and Gram – bacteria, including their superbug forms - even with repeated use!

Lead indication for treatment of sepsis – #1 most expensive condition.



Qualified Infectious Disease Product designation under GAIN Act.

10 years market exclusivity (post approval).

Fast track (life of regulatory process).



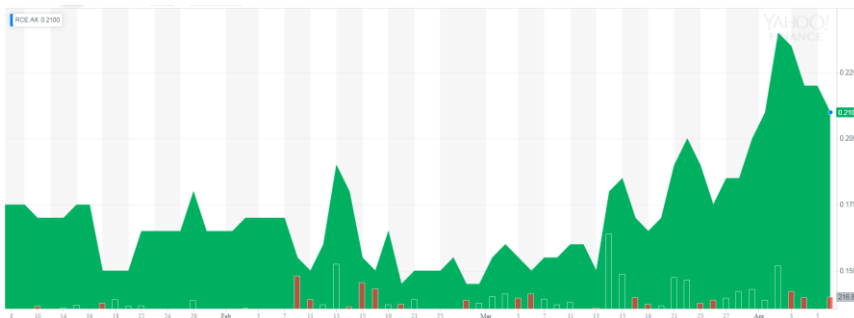
Patented manufacturing, producing to Phase I & II volumes.

Recce Pharmaceuticals Ltd - Capital structure

Major shareholders 31 March 2019

1. G. & O. Melrose*	28.3%
2. Acuity Capital Investment	4.2%
3. J. Graham*	4.0%
4. JP Morgan Nominees*	3.9%
5. R. Gustafson	3.1%

ASX:RCE 3 months



* Held by Executive Directors



recce.com.au

Snapshot

ASX code	RCE
Shares on issue	107.13 million
Share price	AUD 0.19 cents
Market Cap (approx.)	AUD \$20.4 million
Cash and deposits* February 2019	AUD \$1.8 million
Trading range 52 week	AUD 13-24.5 cents
Average daily volume 1 month	311,994

*Recent placement of A\$1.8 million (BC) as of 8th February 2019

Tackling superbugs – RECCE® 327 (video)

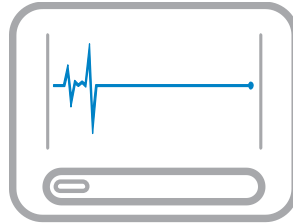


Sepsis – it's a big problem!

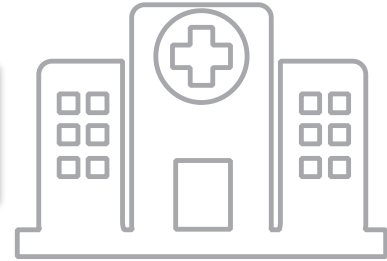
Sepsis affects
+30 million people
worldwide^{*1}



258K deaths
recorded in the US
yearly²



\$24bn in **annual costs**
treated in US hospitals³



- ▶ Sepsis is a life threatening inflammatory response to infection that has spread in the body.⁴
 - Kills more people in the US than **prostate**, **breast** and **lung cancer** combined.⁵
- ▶ **Most expensive condition to treat** - double the average cost per stay across all other conditions.⁶
- ▶ Over 750,000 cases of severe sepsis reported in the US alone.⁷
- ▶ **Currently no drug therapies specifically for the treatment of sepsis.**⁸

Natural antibiotics vs synthetic antibiotics



Natural antibiotics

Pre-formed
natural superbugs

- ▶ All Fungi or Bacteria based
 - “Penicillin allergy is the most common drug allergy and is reported in up to 15 percent of hospitalized patients”¹
- ▶ Only as good as what’s found in nature
- ▶ Has always had naturally occurring superbugs, now multiplying out of control!



Synthetic antibiotics

NO Pre-formed
natural superbugs

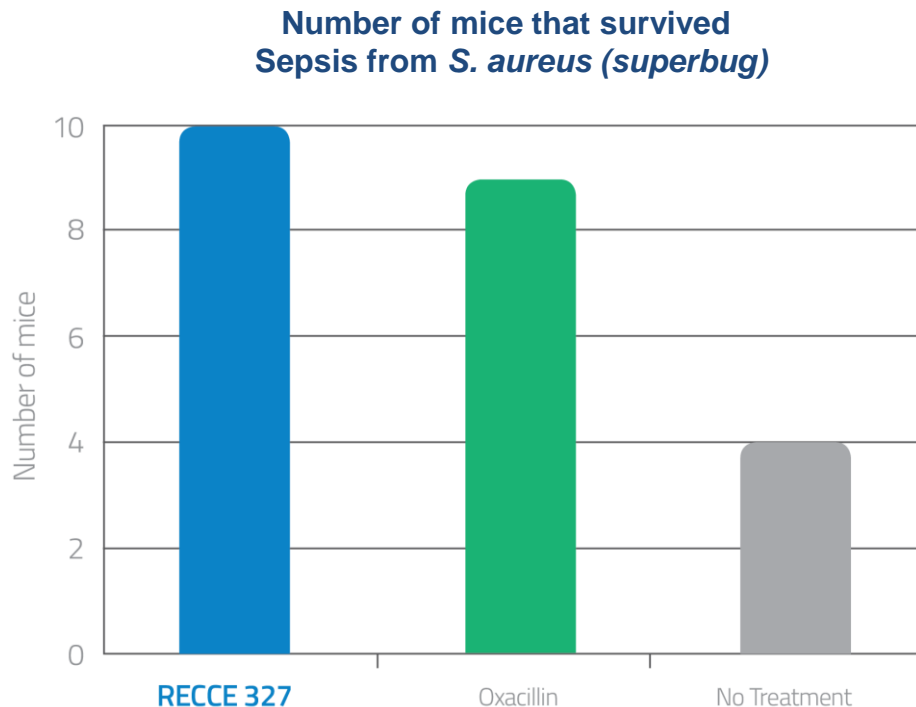
- ▶ Entirely man-made and designed with purpose
- ▶ Universal Mechanism of Action - detailed experimentation demonstrates it does not succumb to superbugs.
- ▶ Contains only what we want - not reliant on what’s found in nature
- ▶ Broad Spectrum capability and maintains its activity even with repeated use!

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.

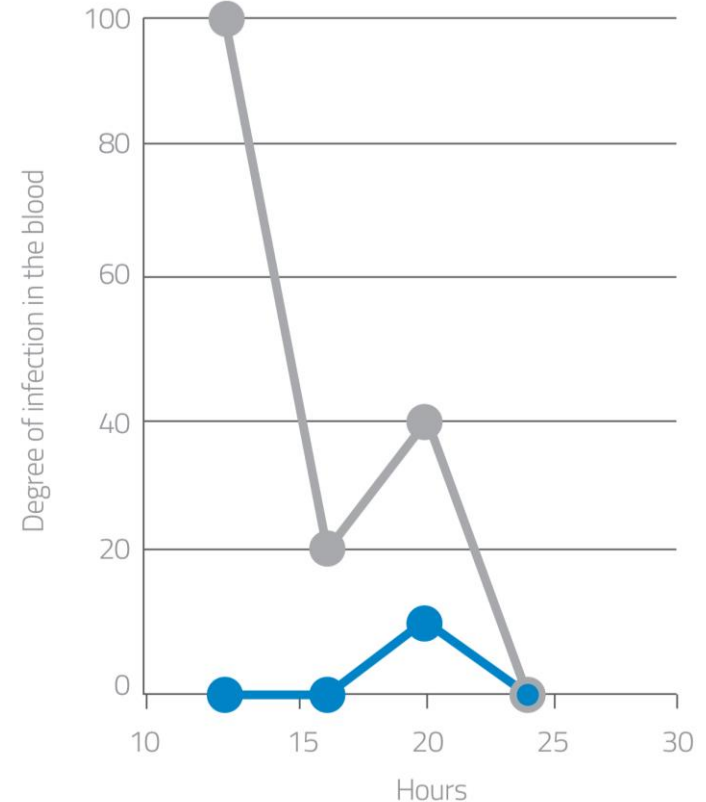


RECCE® Antibiotics – Preventative study*

Controlled study with two groups of mice:

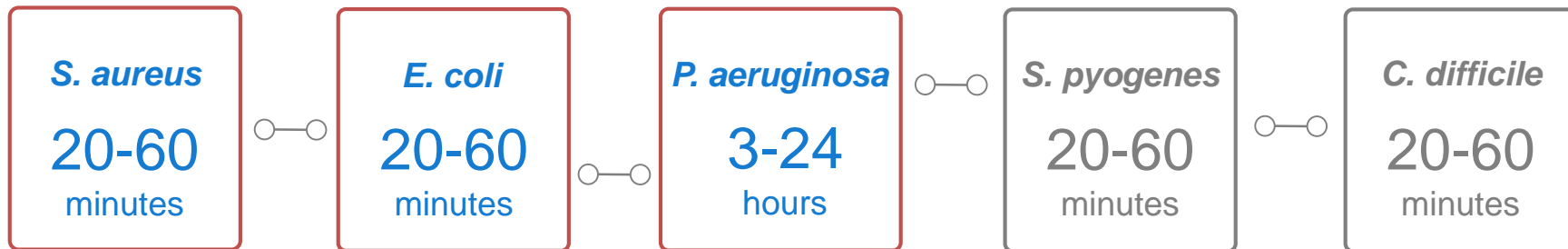
- ▶ **Blue** group represent mice with RECCE® 327 already flowing through blood stream
- ▶ **Grey** group represent mice with no treatment
- ▶ At 0 hours both groups were introduced with significant *S. pyogenes* bacterial burden to the blood stream
- ▶ Due to RECCE® 327 already present in a preventative role, introduction of bacteria to the **blue** group **DID NOT** lead to established infection
- ▶ Results were monitored at 12th hour (per industry standard) to allow bacterial infection to develop in host
- ▶ After the 12th hour, *S. pyogenes* appears to be clearing naturally from the blood – **WRONG**
 - Bacteria in grey group rapidly colonising in the kidneys – commonly resulting in catastrophic organ failure
 - **NOT** in RECCE's case. Bacteria in blood rapidly killed and unable to establish infection in kidneys

Sepsis in mice from
Streptococcus pyogenes

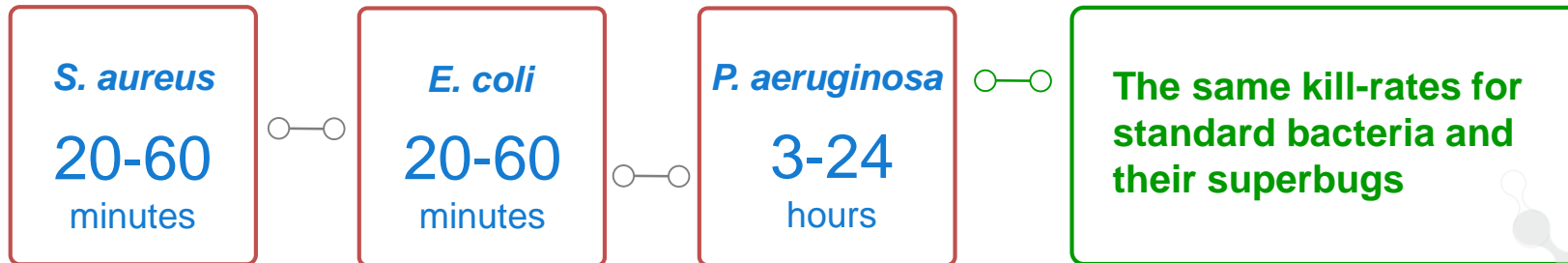


RECCE[®] antibiotics kill at practical speeds

Rates of kill of standard bacteria



Rates of kill of Superbugs



RECCE® antibiotics do not Fail¹

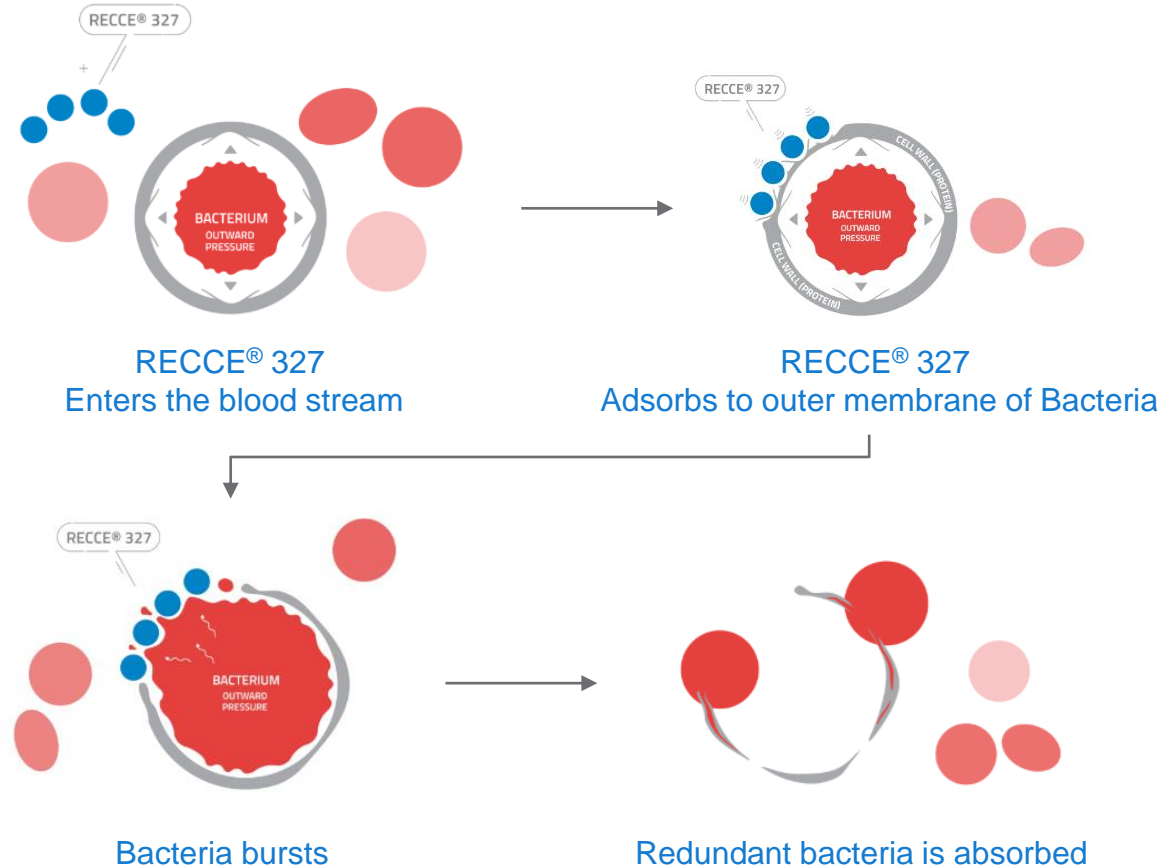
Number of repetitive uses before displaying loss of antibiotic activity



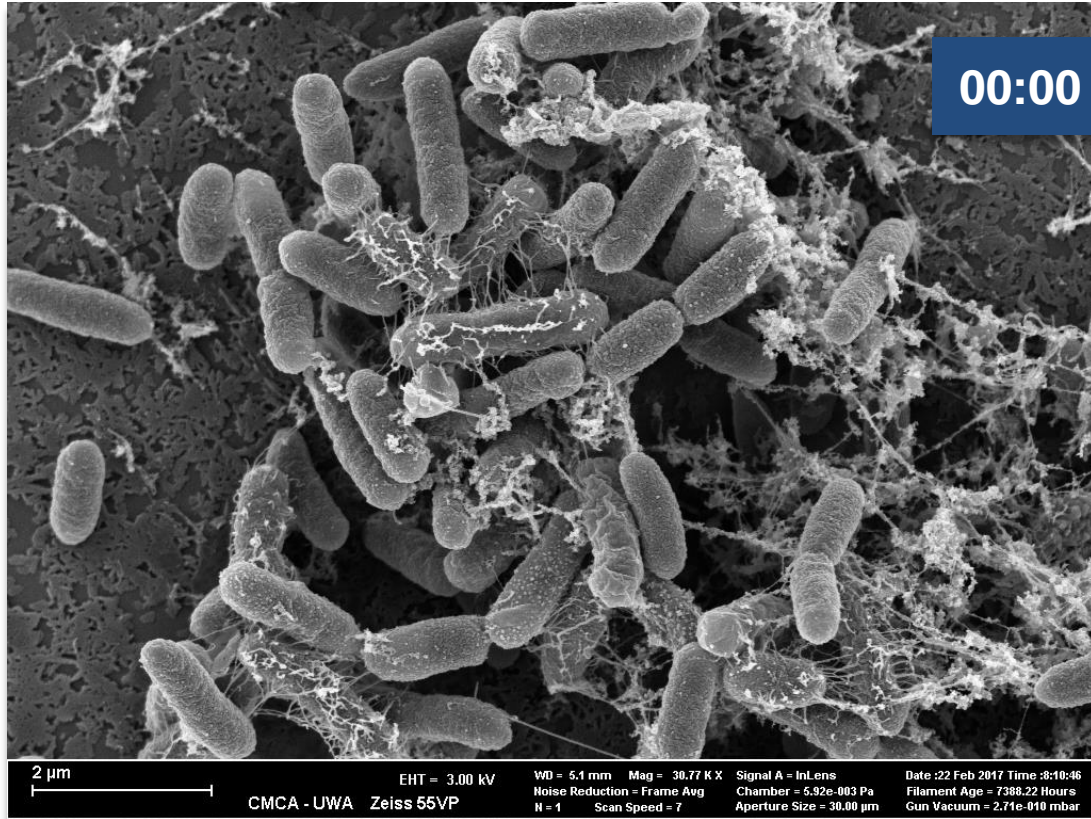
¹After repetitive use, the commercial antibiotic loses activity; **RECCE® antibiotic DOES NOT**

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

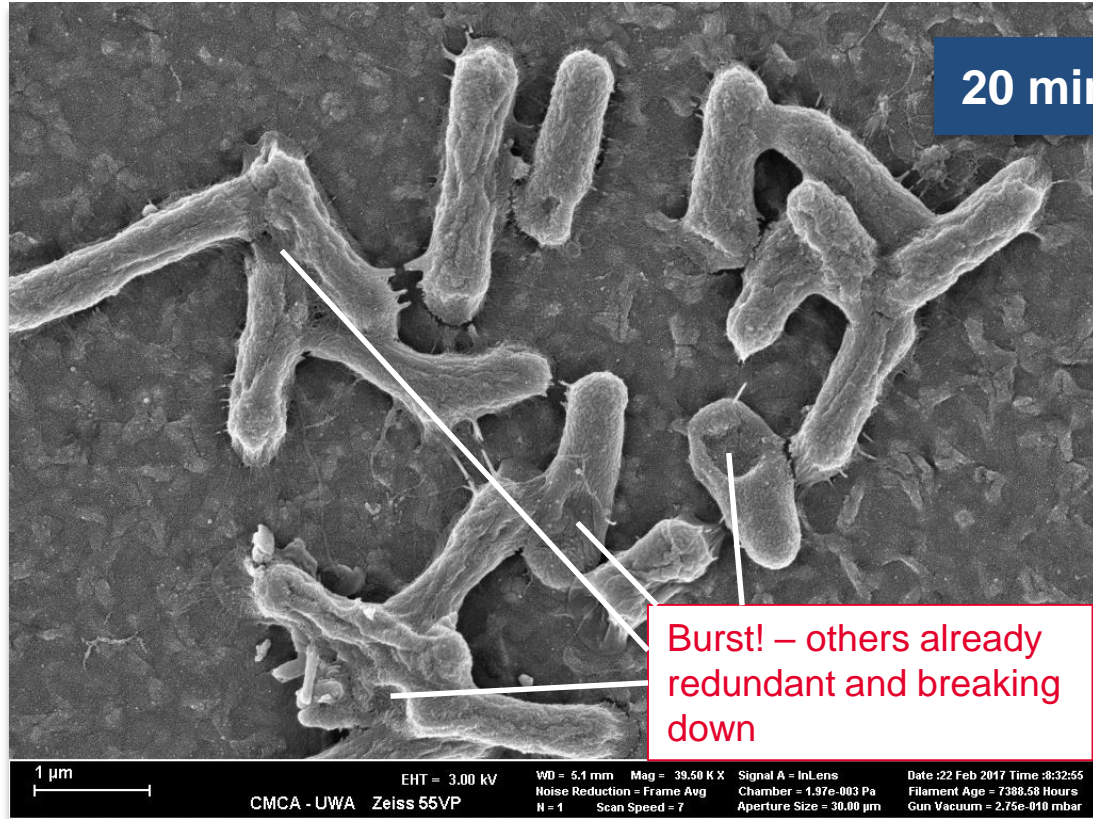


00:00 minutes

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



RECCE® 327 Mechanism of Action in practice



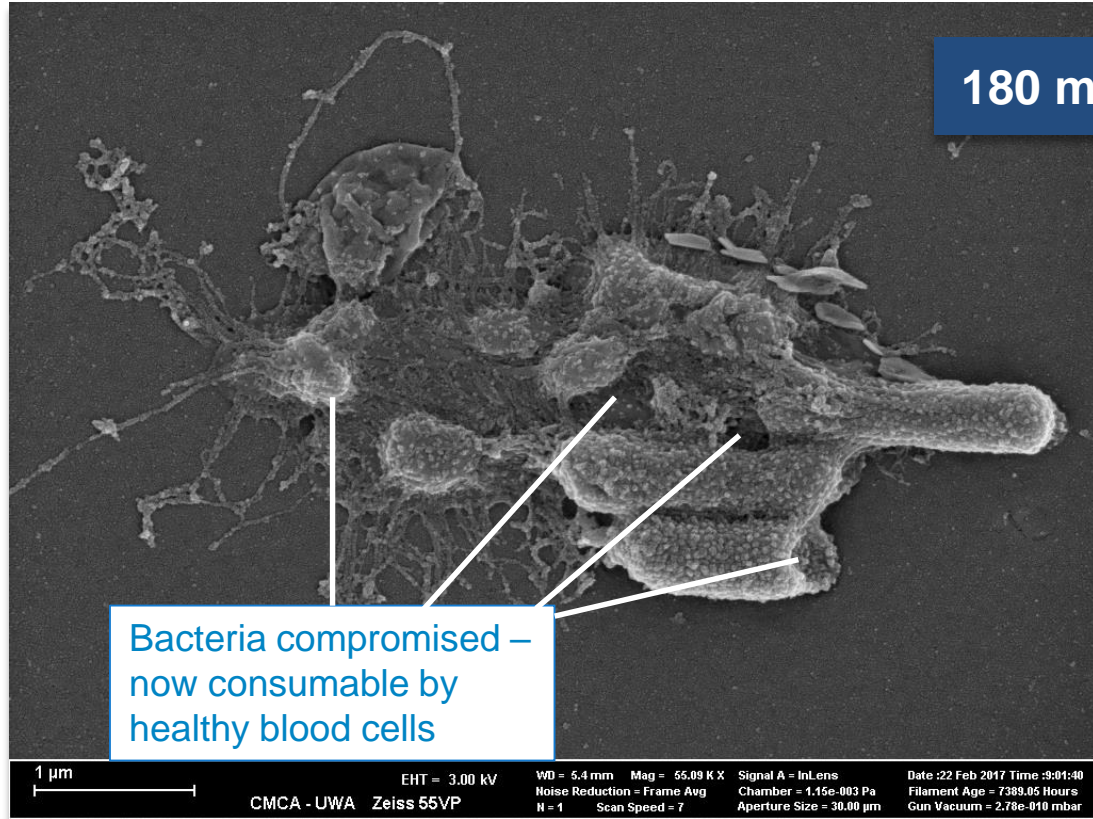
20 minutes

Burst! – others already
redundant and breaking
down

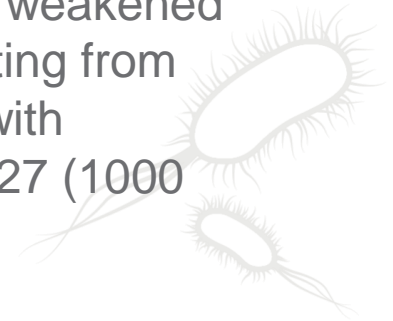
After application
of RECCE® 327,
the *E.coli* bacteria
cell membrane
begins to weaken
and is disrupted



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)



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
- ▶ Indicate a safe therapeutic dosing window



What is Qualified Infectious Disease Product?

- *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.”

Legal status awarded under **US Generating Antibiotic Incentives Now (GAIN) Act**



10 years market exclusivity, starting from the date of New Drug Application approval



Labeled for **fast track designation** – speed the FDA’s review process



QIDP designated drugs to treat serious or life-threatening conditions and fill an unmet medical need



Anticipated further five year exclusivity under **New Chemical Entity (NCE) policy***



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	✓	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 \$/KG
- ▶ No expensive waste – 99.9% product yield.



- ▶ Automated manufacture process taking approximately 1 ¼ hours.



- ▶ Currently producing in volumes to support planned Phase I & II clinical trials.



- ▶ Facility built to pharmaceutical specification.

Board and management structure

Dr Graham Melrose – CEO & Chief Research Officer

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 – Company Secretary (Outsourced – **Automic Legal**)

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.

Global Antibiotic Market Snapshot

In 2017 the global antibiotics market generated

\$42bn

with projections to reach

\$50bn

by 2025.

TGA Special Access Scheme

- ▶ The Special Access Scheme (SAS) refers to arrangements that provide for the import and/or supply of an unapproved therapeutic good for a single patient, on a case by case basis.

3

categories

Category A

- Pathway that may be accessed by a prescribing medical practitioner or by a health practitioner acting on behalf of that medical practitioner, for a patient, who is seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment.

Category B

- Application pathway that can be accessed by health practitioners if patients do not fit the Category A definition.

Category C

- Notification of use of specific therapeutic goods; allows certain types of health practitioners to supply therapeutic goods deemed to have an established history of use.

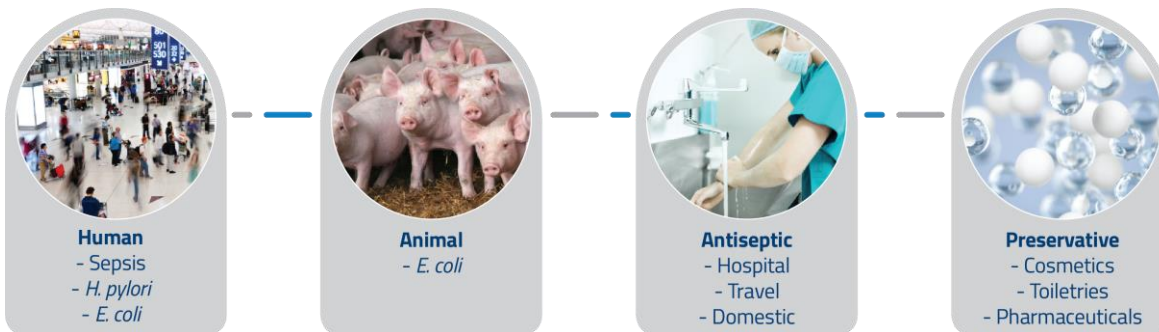


Australian Government

Department of Health
Therapeutic Goods Administration

RECCE® 327 development program

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



SEPSIS (IV – *S. AUREUS*, *E. COLI*)

GASTRITIS (ORAL – *H. PYLORI*)

INTESTINAL (ORAL – *E. COLI*)



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



Qualified Infectious Disease
Product (QIDP) Designation



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

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