

ASX Announcement

Recce to Present at MST Access Investor Conference

Sydney Australia, 17 June 2021: Recce Pharmaceuticals Ltd (**ASX:RCE**) (**FSE:R9Q**) (**Company**), is pleased to announce that it has been invited to present at the MST Access Australian Micro & Small Caps Conference 2021.

Presentation is to be given by CEO Mr James Graham today, Thursday 17 June at 12.30pm AEST.

Please find attached the presentation. To join, please click the webinar link below:

<https://mstfinancial-au.zoom.us/j/82826045695>

This announcement has been approved for release by Recce Pharmaceuticals CEO

About Recce Pharmaceuticals Ltd

Recce Pharmaceuticals Ltd (ASX: RCE) is pioneering the development and commercialisation of New Classes of Synthetic Anti-Infectives designed to address the urgent global health problems of antibiotic resistant superbugs and emerging viral pathogens.

Recce's anti-infective pipeline is unique and comprised of broad-spectrum synthetic polymer antibiotics RECCE[®] 327, RECCE[®] 435, and RECCE[®] 529 for viral infections with unique mechanisms of action against hyper-mutation on bacteria and viruses, respectively.

Patented lead candidate RECCE[®] 327 as an intravenous therapy, is being developed for treatment of serious and potentially life-threatening infections including sepsis due to Gram-positive and Gram-negative bacteria including their superbug forms. Recce's new antibiotic compound, RECCE[®] 435, has been formulated for oral use.

The FDA has awarded RECCE[®] 327 *Qualified Infectious Disease Product* designation under the *Generating Antibiotic Initiatives Now* (GAIN) Act – labelling it for Fast Track Designation, plus 10 years of market exclusivity post approval. Further to this designation, RECCE[®] 327 has been included on The Pew Charitable Trusts *Global New Antibiotics in Development Pipeline* as the only synthetic polymer and sepsis drug candidate in development.

Recce wholly owns its automated manufacturing, ready to support first-in-human clinical trials. Recce's anti-infective pipeline seeks to exploit the unique capabilities of RECCE[®] technologies targeting synergistic, unmet medical needs.



ASX: RCE, FSE: R9Q

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MST Access Presentation

ASX:RCE, FSE:R9Q

June 2021

Disclaimer

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Management Structure



Dr John Prendergast – Chairman

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.



James Graham – Chief Executive Officer

BCom (Entrepreneurship), GAICD

5 years as former Executive Director. Invested along-side shareholders in most capital rounds since inception. Background in marketing, business development and commercialisation of early-stage technologies.



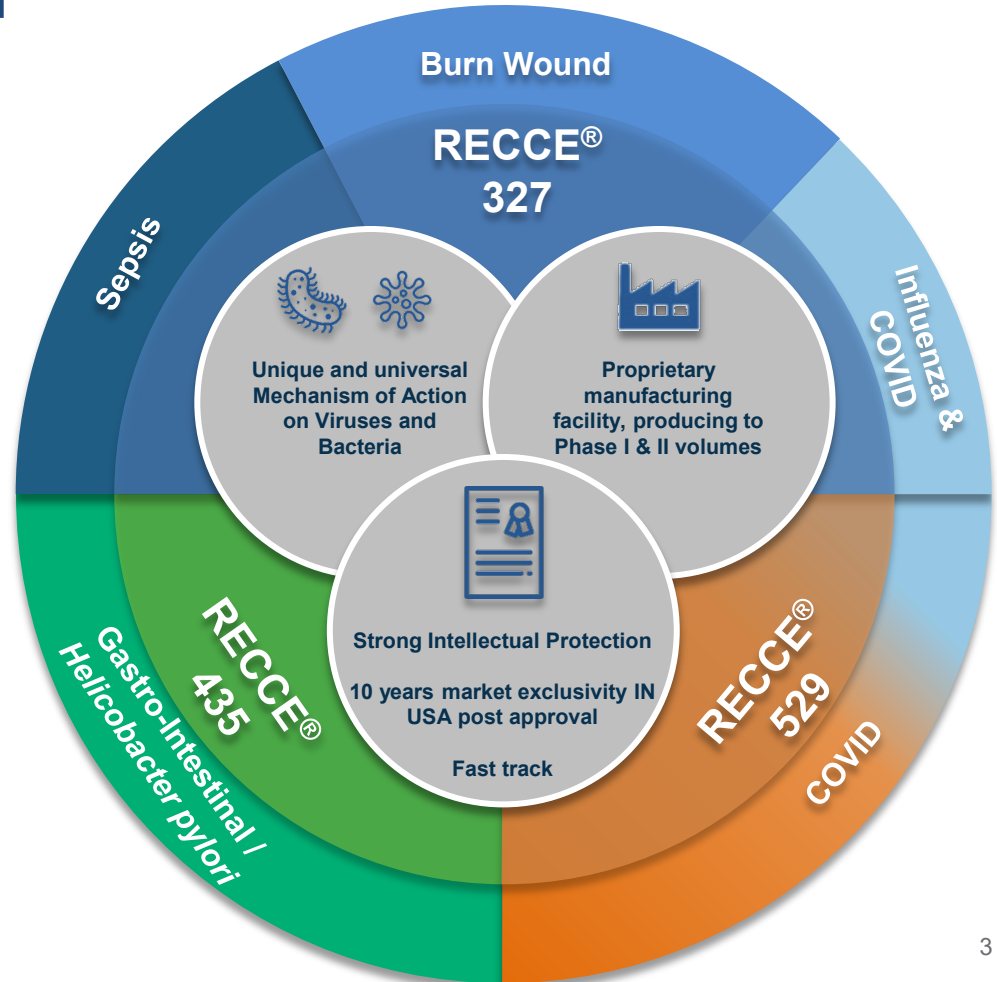
Michele Dilizia – Chief Scientific Officer

BSc (Med Sci), Grad Dip Bus (Mkting), BA (Journ), GAICD, MASM

Co-inventor and qualified medical scientist; specialisation in medical microbiology and regulatory affairs requirements.

A Versatile Technology Platform

- ▶ **Anti-infective** focused Biotech company targeting both bacterial and viral indications
- ▶ **Strong IP** and **own manufacturing** capability
- ▶ **Versatile platform** delivering oral, intravenous and spray formulations for a range of use-cases
- ▶ Designed to safely provide treatment **without developing resistance** over time
- ▶ Multiple opportunities with RECCE® 327 interim **first in human** data expected in 2021



Strong Pipeline

Over Various Indications and Upcoming Inflection Points

327

435

529

Asset Route of administration	Indications	Discovery	Preclinical	Phase I	Phase II	Phase III	Next data readout	Market Size
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Anti-bacterial programs

R327 Intravenous & Intranasal	Serious/life threatening bacterial infections including sepsis	[Progress bar]					Phase I interim data readout Q4 2021	47-50 million cases worldwide
	Pre-sepsis - kidney & UTI infections	[Progress bar]						
R327 Topical	Wound infections including infected burns	[Progress bar]					Phase I/II readout Q4 2021	11 million burn wound cases requiring medical intervention. Majority of which escalate to infection
R435 Oral R529	<i>Helicobacter pylori</i> in stomach ulcers	[Progress bar]						Up to 4.4 billion worldwide

To start post Phase II in sepsis



Anti-viral programs

R327 Nasal	COVID & Influenza	[Progress bar]						
R529 IV and Intranasal	COVID	[Progress bar]						

RECCE[®] 327 as an Antibiotic

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!



Sepsis – it's a big problem!

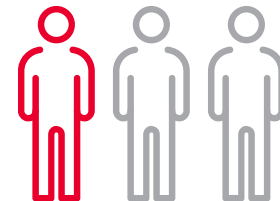
48.9 million incident cases of **sepsis** recorded worldwide¹



11 million sepsis related **deaths** recorded²



One in three patients who **die** in hospital have sepsis³



- ▶ Sepsis is a life-threatening inflammatory response to infection that has spread in the body.
 - Kills more people in the US than **prostate, breast cancer** and **HIV/AIDS** combined.⁴
- ▶ Has been the **most expensive condition to treat** in the last 8 years - **double the average cost per stay across all other conditions.**⁵
- ▶ Currently no drug therapies specifically for the treatment of sepsis.⁶

1,2,3 – The Lancet

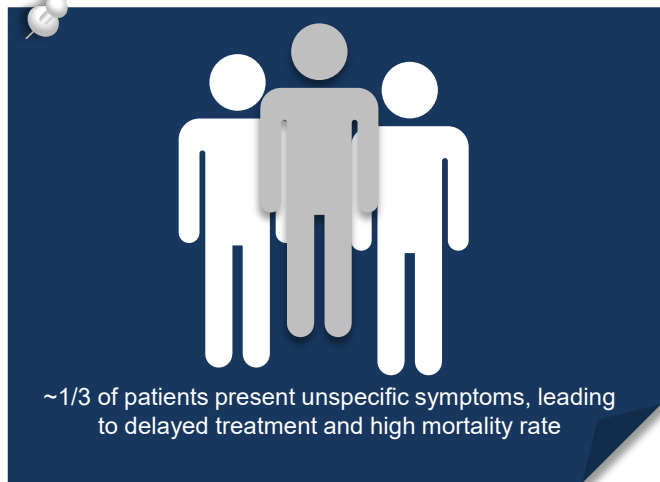
4 – BioMed Central

5 – University of Texas

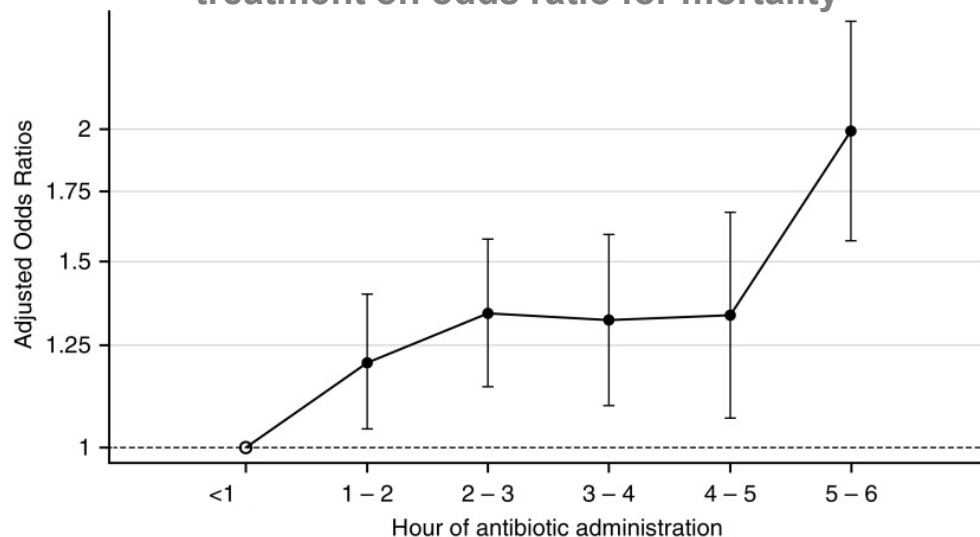
6 – International Medicine Journal RACP

Treatment Paradigm

- ▶ Current treatment paradigm relies on:
 - ▶ Introducing broad spectrum antibiotic(s)
 - ▶ Running antibiograms
 - ▶ Adjusting antibiotics based on antibiogram results



Impact of delayed antibiotic treatment on odds ratio for mortality¹

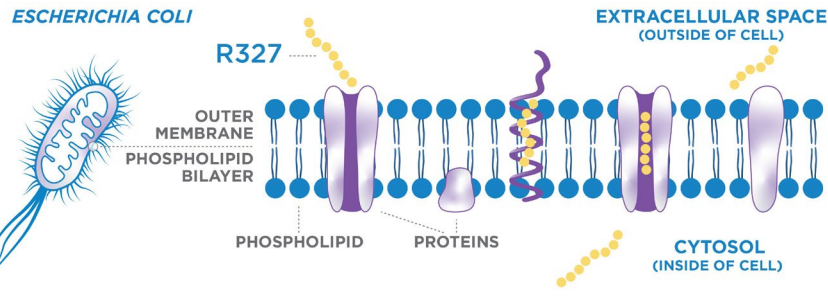


Early treatment with the correct antibiotic is key to patients' outcome

Mortality from sepsis increases by as much as 8% for every hour that treatment is delayed²

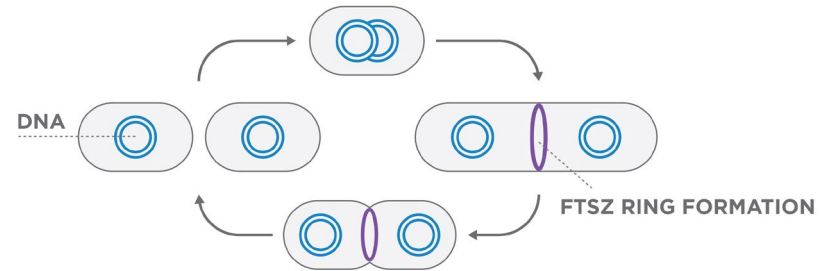
Hypothesized Mechanism of Action

Stage 1



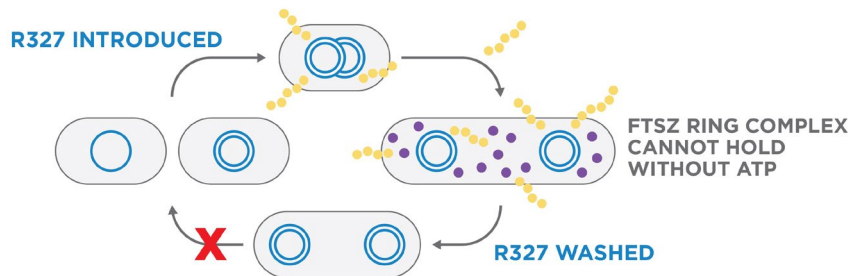
R327 permeabilizes cell membrane & enters the cell

Stage 2



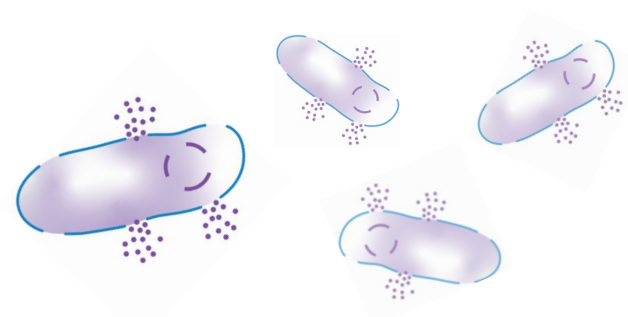
R327 interrupts bacterial cellular energetics via ATP Synthesis

Stage 3



Cellular division & non-dividing cell functions are disrupted

Stage 4



R327 rapidly & irreversibly bactericidal & at high concentrations cell lysis

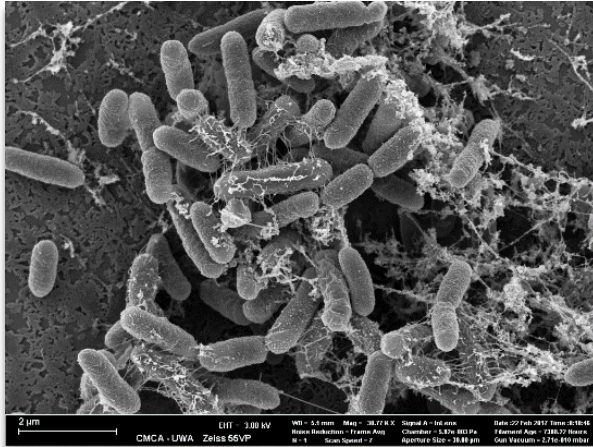
RECCE® 327 Mechanism of Action in practice

327

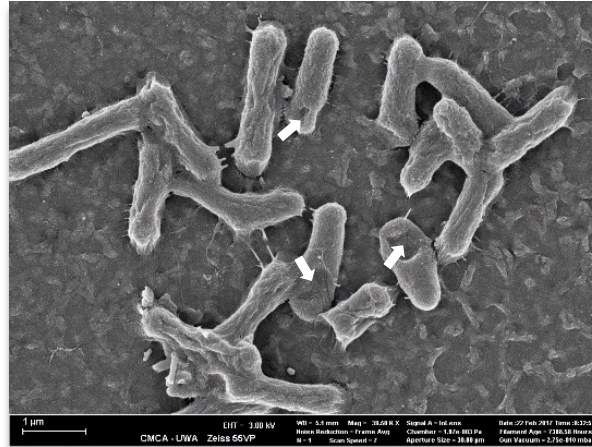
435

529

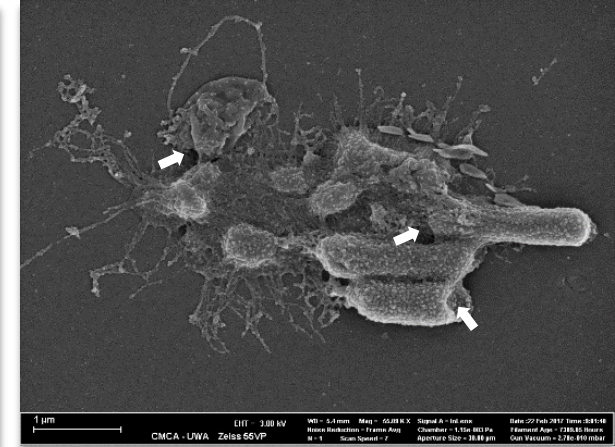
00 minutes



20 minutes



180 minutes



Before application of R327, the *E. coli* bacteria cells are healthy, smooth and intact

After application of R327, the *E. coli* bacteria cell membrane begins to weaken and is disrupted

E. coli bacteria cells (10e6 cfu/ml) having their outer membrane weakened – and bursting from treatment with R327 (1000 ppm)

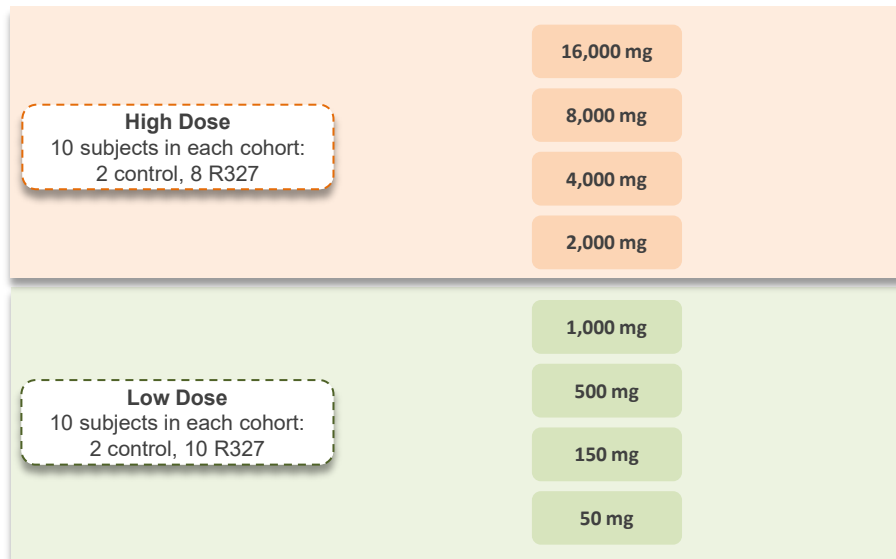


Phase I Human Clinical Trial

Safety and Tolerability Interim Data Expected Late 2021

- ▶ Study to assess IV infusion of RECCE® 327 in 80 healthy male subjects as a single ascending dose
- ▶ Formal subject recruitment expected to open for enrolments shortly
- ▶ Randomized, double blind, placebo controlled, safety, tolerability and pharmacokinetics study
- ▶ Single dose of a 1-hour via IV infusion at a uniform rate in hospital setting
- ▶ Primary endpoint: vital signs, 12-lead ECG parameters, clinical chemistry, hematology, and urinalysis.

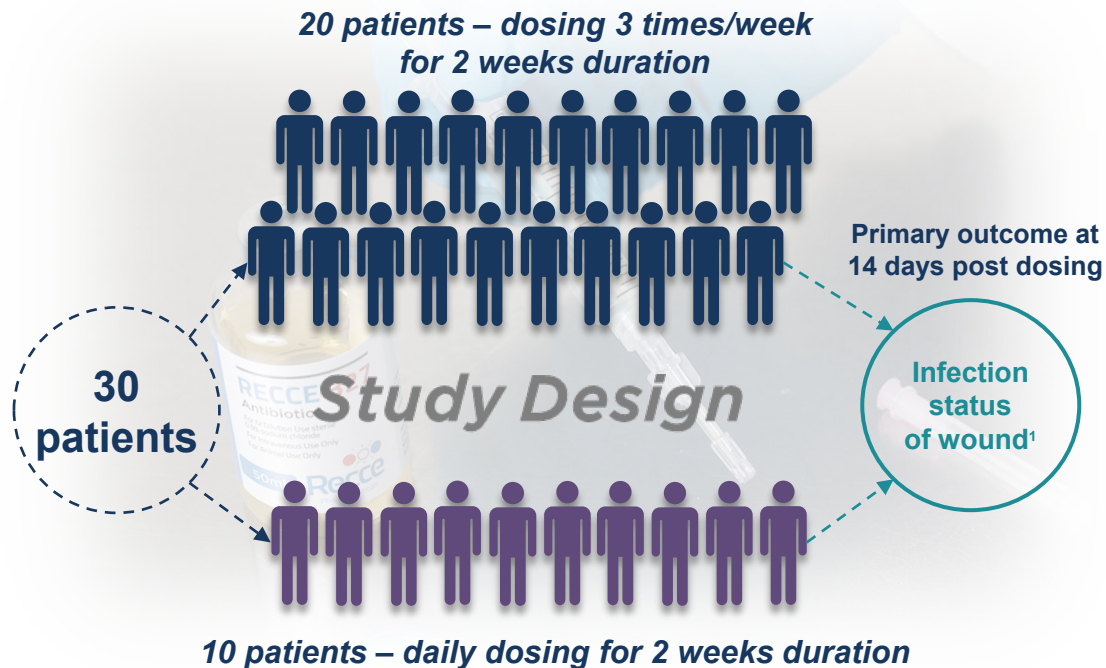
Interim data expected late-2021
Full data expected early-2022



Topical RECCE® 327 - Phase I/II

Burn wound infections – Interim Data expected in Q3 2021

- ▶ **Phase I/II** to assess Topical RECCE® 327 Topical in burn wound infections
- ▶ Sponsored by the South Metropolitan Health Service, Department of Health, Government of Western Australia
- ▶ **Trial Investigators:**
 - Dr Edward Raby (Clinical Microbiologist and Infectious Diseases expert at Royal Perth and Fiona Stanley Hospitals)
 - Professor Fiona Wood (Head of Burns) – world-renowned burns specialist and spray-on skin pioneer
 - Dr Chris Heath (Head of Infectious Diseases)
- ▶ Full data expected in Q4 2021



Burn Wound Infections Affects ~60%¹ of Patients

11 million cases requiring medical intervention annually²

MRSA one of the leading organisms causing invasive infection in burns across the world, burn units reporting rates of infection greater than 50%³

Multiple studies over the last decade have shown that 42%–65% of deaths in burn victims are attributable to infection⁴



1 - <https://pubmed.ncbi.nlm.nih.gov/27246641/>

2 - <https://www.who.int/news-room/fact-sheets/detail/burns>

3 - <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4790211/#:~:text=aureus%20now%20is%20one%20of,%25%20%5B9%2C10%5D>

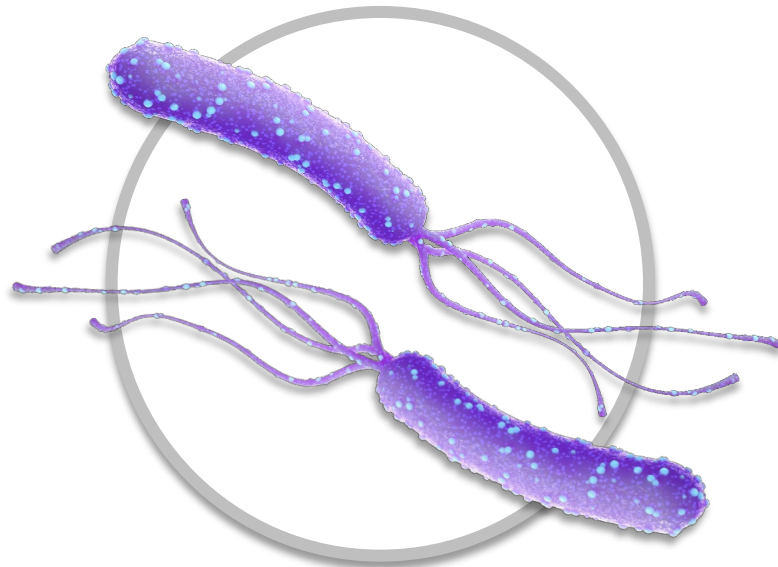
4 - <https://academic.oup.com/cid/article/65/12/2130/4372276>

RECCE® 435 - Targeting *Helicobacter pylori*

R435 in *Helicobacter pylori* (*H. pylori*) infection

Potency as an Oral Formulation

- ▶ *H. pylori* is a common type of bacteria that grows in the digestive tract and has a tendency to attack the stomach lining
- ▶ It is **estimated to affect 4.4 billion people worldwide** (over half of the global population)
- ▶ **Approximately 89% of all gastric cancers are attributed to *H. pylori* infection** and the eradication of this infection has known to reduce gastric cancer incidence
- ▶ Global unmet medical need for the treatment of *H. pylori* with no first-line therapy curative in all patients
- ▶ Recce in agreement with Murdoch Children's Research Institute to conduct pre-clinical studies to tackle this deadly pathogen
- ▶ RECCE® 435's potential as an oral formulation to be assessed for the treatment of *H. pylori* infections



Helicobacter pylori

RECCE® 435 Efficacy

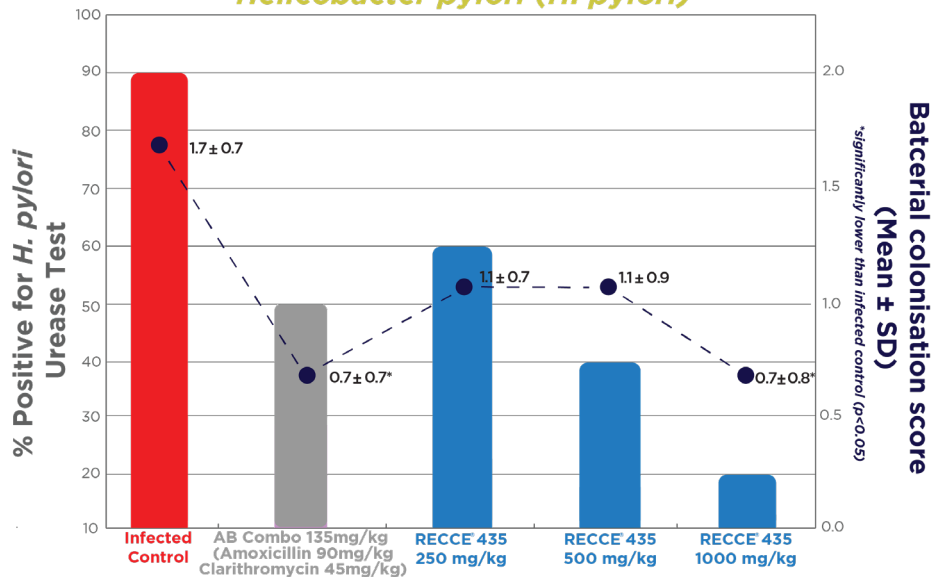
Efficacious at Reducing *H. pylori* Colonisation

- ▶ Dose-dependent efficacy was seen at all doses with significant reduction in bacterial load
- ▶ High solubility and antibacterial effect supportive of a 'targeted' oral therapy for stomach infection
- ▶ Two weeks post infection with bacteria isolated from a duodenal ulcer patient, rats were treated twice a day for 7 days with:

10 rats Control	No treatment
10 rats Control	Amoxicillin + Clarithromycin
10 rats Treatment 1	RECCE® 435 250 mg/kg
10 rats Treatment 2	RECCE® 435 500 mg/kg
10 rats Treatment 3	RECCE® 435 1,000 mg/kg



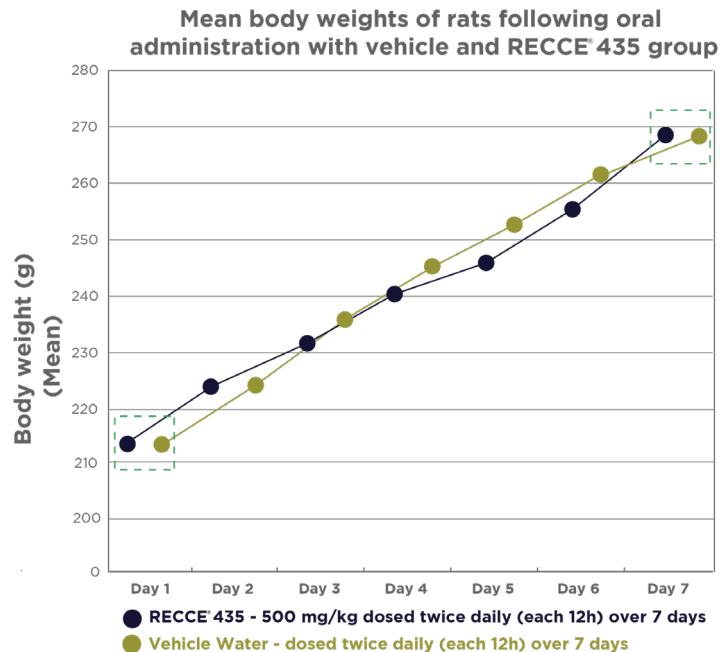
RECCE® 435 Oral Rat Study *Helicobacter pylori* (*H. pylori*)



Group	Group ID	Rats	Urease test		% Positive for <i>H. pylori</i> [Urease Test]
			Positive	Negative	
1	Uninfected control	10	0	10	0
2	Infected control	10	9	1	90
3	AB Combo 135 mg/kg (Amoxicillin 90 mg/kg + Clarithromycin 45 mg/kg)	10	5	5	50
4	Infected + RECCE® 435 - 250 mg/kg	10	6	4	60
5	Infected + RECCE® 435 - 500 mg/kg	10	4	6	40
6	Infected + RECCE® 435 - 1000 mg/kg	10	2	8	20

RECCE[®] 435 Safety Oral Study in Rats

- ▶ RECCE[®] 435 / Vehicle were administered twice daily for 7 days
- ▶ Data indicates their feeding habits, which contributes to weight gain
- ▶ RECCE[®] 435 had no impact on weight gain/loss vs control
- ▶ Supports overall general and gastrointestinal health



Mean body weights of rats following oral administration with vehicle and RECCE [®] 435 group				Body weight (g) (Mean ± SD)			
Days	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Vehicle Water – dosed twice daily (each 12h) over 7 days	213 ± 8.09	224.4 ± 6.73	236.2 ± 4.82	246 ± 5.15	253.2 ± 4.15	262.6 ± 3.65	268.2 ± 5.81
RECCE [®] 435 - 500 mg/kg dosed twice daily (each 12h) over 7 days	213.4 ± 4.56	223.4 ± 9.32	231.6 ± 7.7	240 ± 4.74	246.8 ± 5.89	255.2 ± 9.65	269.4 ± 5.77



R435 Pre-clinical Studies

Further Pre-clinical Studies planned with R435 against *H. pylori*

- ▶ Murdoch Children's Research Institute (MCRI) to evaluate *in-vivo* antimicrobial activity of RECCE® 435 oral formulation against *H. pylori* in pre-clinical studies program
- ▶ Study led by *H. pylori* infectious disease expert Prof. Philip Sutton
 - ▶ Using mice as a highly validated animal model for *H. pylori*
- ▶ MCRI is one of the top three children's health research institutes worldwide for research quality and impact
- ▶ Recce and MCRI will work together on the oral antibiotic dosing program with a particular focus on optimal dosing and the effect of RECCE® 435
- ▶ Anticipated completion at approximately mid-2022, at which time Recce may pursue a human clinical trial second half of 2022



***RECCE[®] 327 and RECCE[®] 529 as
Anti-virals against COVID-19***

SARS-CoV-2 Antiviral Program



Despite vaccinations availability, an effective pharmaceutical **treatment against all current and future strains of COVID-19** is needed to gain control over the global pandemic



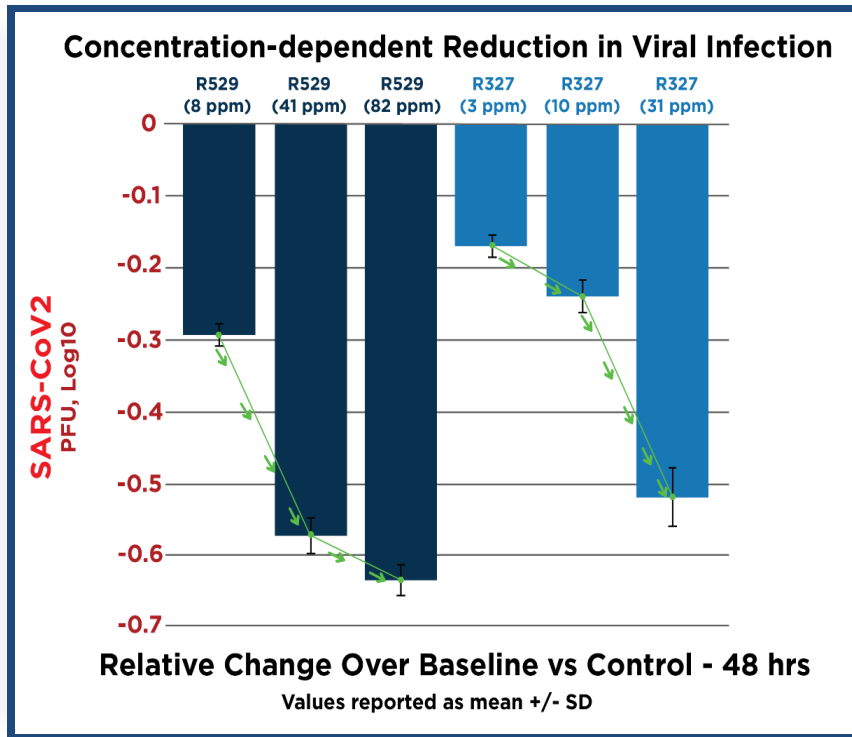
RECCE® 327 was **selected as priority 1 test candidate** for testing against COVID-19 - in the **Australian government SARS-CoV-2 Antiviral program**



Therapeutic anti-viral treatment focus with added potential benefit **against secondary bacterial infections**



Studies in mammalian cells showed **safety and efficacy in preclinical studies**



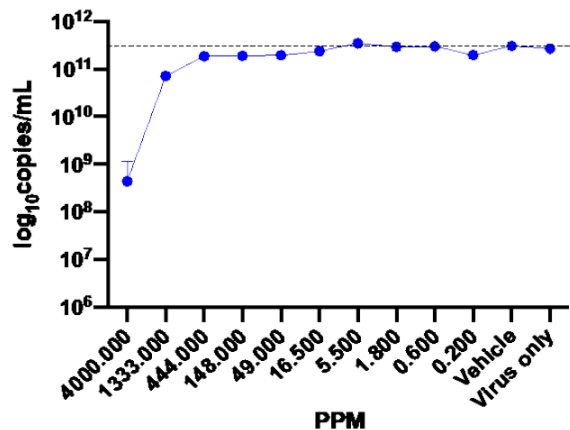
RECCE® 327 and **RECCE® 529** have shown concentration-dependent reduction of SARS-CoV-2 virus in Vero (monkey) cells

SARS-CoV-2 Antiviral Program

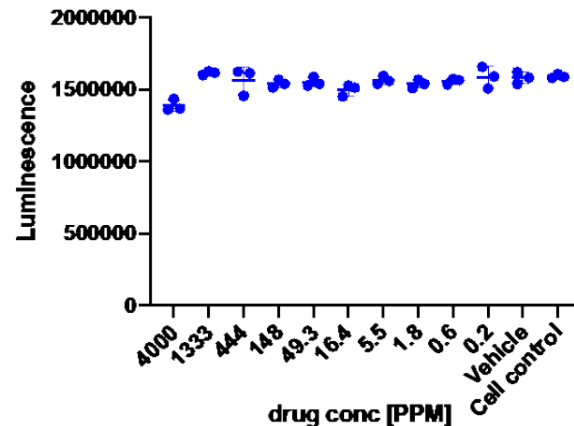
- ▶ At 4,000ppm, RECCE® 327 demonstrated *in-vitro*:
 - ▶ **99.9% efficacious with a 3-log drop in viral genome copies**
 - ▶ **No virus detectable by virus titration**
 - ▶ **No virus detectable by virus titration**
 - ▶ Some cytotoxicity detected at 4,000ppm but not at lower concentration
- ▶ International *in-vivo* studies expanded to include new UK and South African COVID strains.

RECCE 327 RT-PCR and Cell Viability Data

Recce327 viral genome copy number



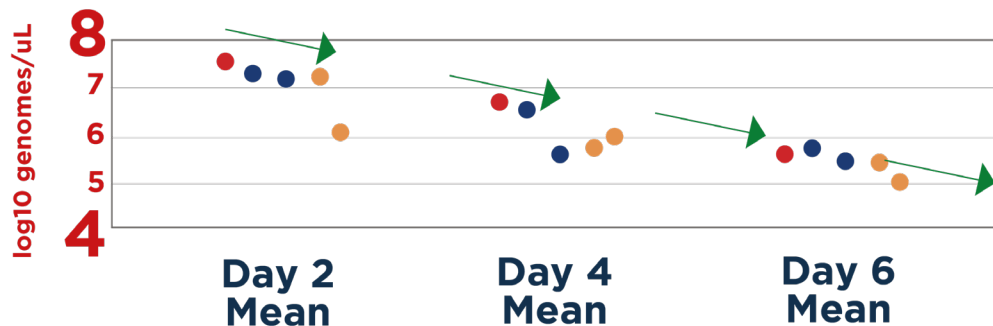
Recce Cell viability



Nasal administration

RECCE® 327 and RECCE® 529 in Hamsters

Nasal Wash Viral Titres in Hamsters



Key

- Placebo (Saline Wash)
- R327 Low (200 mg/kg)
- R327 High (400 mg/kg)
- R529 Low (100 mg/kg)
- R529 High (200 mg/kg)

Understanding logs*

A 1-log kill is a 90% reduction

A 2-log kill is a 99% reduction

A 3-log kill is a 99.9% reduction

5 groups with 8 hamsters each, administered with:

Saline nasal wash	R327 200 mg/kg	R327 400 mg/kg	R529 100 mg/kg	R529 200 mg/kg
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Drug administered twice daily for 5 days
qPCR of samples from nasal wash at day 2,4,6

- ▶ RECCE® 327 and RECCE® 529 demonstrated **dose-dependent activity *in-vivo*** against SARS-CoV-2 virus in Syrian golden hamsters
- ▶ Data conveyed a mean log reduction within groups on Day 4 where low **R529 dose achieved a log reduction in the order of 1.5 logs** and a high dose of **R327 achieved log reduction of 1.25 logs**



Full Control through Strong IP and Manufacturing



Patents

Three families across all major markets

Recce's patent portfolio includes more than 20 issued patents and patent applications in the world's major markets, including the United States, Europe, Japan, China and Australia.

Filed	Patent Family 1	Expiry	Patent Family 2	Expiry	Patent Family 3	Expiry
Australia	✓	2028	✓	2035	Pending	2037
USA	✓	2029	✓	2035	Allowed	2037
Europe	✓	2028	✓	2035	✓	2037
Japan	✓	2028	✓	2035	✓	2037
China	✓	2028	Pending	2035	Allowed	2037

✓ Granted

Patent Family 1 – Antimicrobial Polymers and their Compositions

- ▶ Family 1 group relates to the Company's unique and highly economical manufacturing process and use of the polymer in treatment of diseases

Patent Family 2 – Copolymer for use in Method of Treatment of a Parenteral Infection

- ▶ Family 2 relates to the method of manufacture, administration and application to treat a broad range of common human infections.

Patent Family 3 – Anti-Virus Agent and Method for Treatment of Viral Infection




- ▶ Family 3 relates to a method of treatment of a broad range of viral infections, particularly parenteral viral infection



Insourced Manufacturing Capabilities



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 hour
-  ▶ 500 doses per fully automated run
-  ▶ Currently producing in volumes to support planned Phase I & II clinical trials.
-  ▶ Facility built to pharmaceutical specification.
-  ▶ Packaging and labelling to international 'tamper-proof' standards



Recce Pharmaceuticals Ltd – Capital Structure

Snapshot

Tickers ASX:RCE, FSE:R9Q

Amount Raised to Date AUD \$46 million

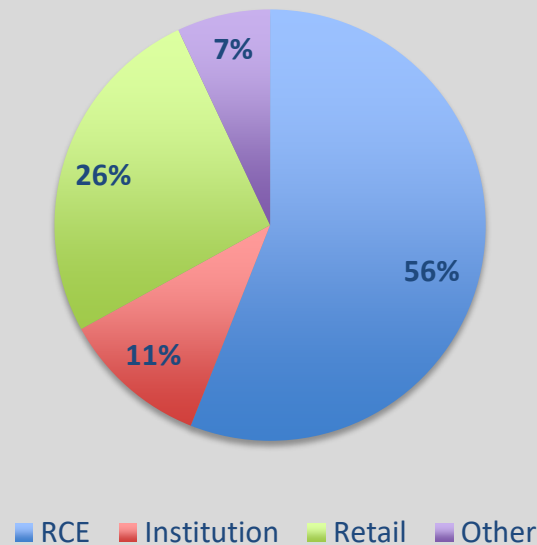
Market Cap (approx.) AUD \$185 million
15 June 2021

Cash and deposits AUD \$22.9 million
31 March 2021

Outstanding shares 173.8 million

Average daily volume 265.8K
3 months

Top 20 Shareholders Distribution*



*Top 20 as of 16 June 2021



Investment Summary



Proprietary **new class of anti-infectives** against bacteria and viruses, protected by Composition of Matter Patent.



Fast development plans initially targeting: **Sepsis, Burn wounds, Helicobacter Pylori and COVID-19.**



Strong pre-clinical data package demonstrating **high bactericidal activity** combined with **very good safety** at expected human therapeutic range.



State of the Art manufacturing capacities ensuring **highly attractive manufacturing costs and scalability.**



R327 Phase I clinical trial patient dosing in Q3 2021 delivering interim data by late 2021.
Topical Phase I/II human clinical study of R327 is underway delivering full data Q4 2021 with interim data throughout.



Robust financial position to deliver clinical data.





Thank you

James Graham

Chief Executive Officer

Recce Pharmaceuticals

ASX:RCE; FSE:R9Q

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