Recce Pharmaceuticals

Corporate Presentation

March 2023

recce.com.au

ASX:RCE FSE:R9Q

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Board Structure

Dr John Prendergast
Executive Chairman
(Shares: 250,000)
(Options: 2,175,000)

James Graham
Chief Executive Officer
(Shares: 6,031,932 – 3.39%)
(Options: 2,250,000)

Michele Dilizia
Chief Scientific Officer
(Shares: 3,543,485 – 2.0%)
(Options: 1,500,000)

Justin Ward
Executive Director &
Principal Quality Chemist
(Shares: 158,966)
(Options: 600,000)

Alistair McKeough
Non-Executive Director
(Shares: 25,000)
(Options: 1,125,000)

Dr Alan Dunton
Non-Executive Director
(Shares: 60,000)
(Options: 1,125,000)

Justin Reynolds
Outsourced CFO

Maggie Niewidok
Company Secretary

Investment Highlights

*Proprietary **first-in-class anti-infectives** against bacteria and viruses*

*Multiple shots on goal, initially pursuing four indications: **Sepsis, UTI, Burn wounds and Diabetic Foot Ulcers***

***Multiple Phase I and Phase II clinical programs**, addressing unmet medical needs*

***The global antibiotics market was US$38.08 billion** in 2021 **projected to grow to US$45.30 billion** in 2028 at a CAGR of 2.5%*

Multiple near-term clinical readouts over the next 6-18 months

A Versatile Technology Platform

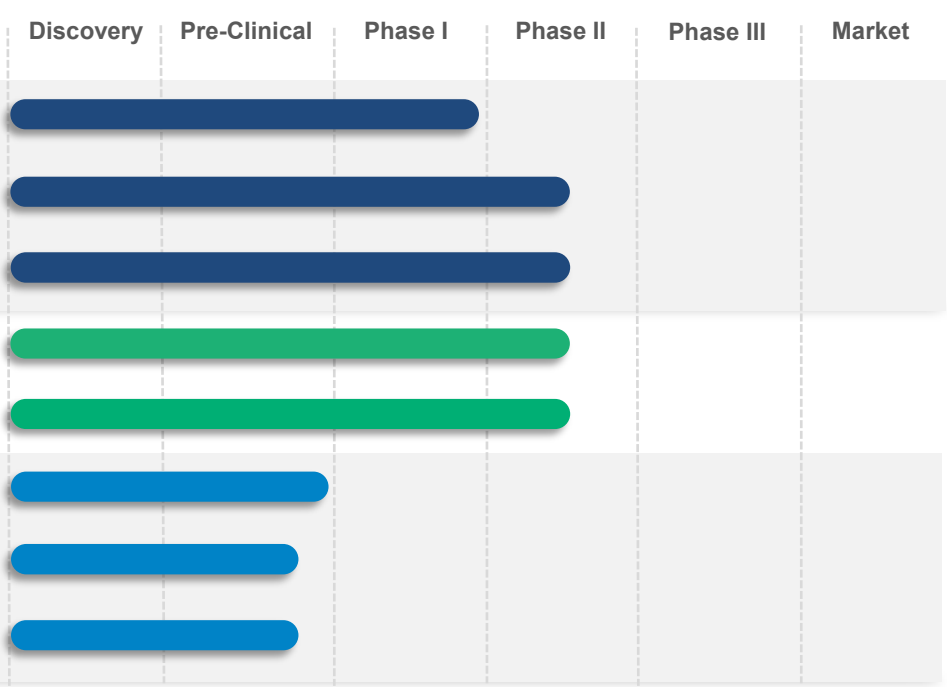
- Clinical-stage biotech company developing **Anti-infectives** targeting both bacterial and viral indications
- **Strong IP** and **own manufacturing** capability
- Qualified Infectious Disease Product designation
  - 10 years market exclusivity plus fast track approval*
- **Versatile delivery platform** – oral, intravenous and topical formulations
- Designed to safely provide treatment **without developing resistance** over time
- Multiple infectious disease opportunities with RECCE® 327

**Awarded by the US FDA in 2017 for R327 bacteraemia (broad-spectrum bacterial sepsis). Time starts only from potential market approval.*

Strong Pipeline

Over Various Indications and Upcoming Inflection Points

Asset and Route of Administration	Indications
R327 Intravenous*	Serious/life threatening bacterial infections including sepsis
	Urinary tract infections including urosepsis
	Multidose, early stage sepsis efficacy study
R327 Topical*	Wound infections including infected burns
	Diabetic Foot Ulcers
RCE Compounds*	*Mycobacterium abscessus* pre-clinical program
	Bacterial Sinusitis pre-clinical program
	Additional TBA pre-clinical program



Anti-bacterial program

Empowering Clinicians with a New Class of Antibiotics

The need for new antibiotics has never been greater

- **Initial resistance to use** new approved drugs due to antibiotic resistance
- "**New antibiotics**, able to kill drug-resistant bacteria, is **essential** to saving modern medicine."
  - *Wellcome Trust*
- "**Lack** of **new antibiotics threatens** global efforts to contain drug-resistant infections."
  - *World Health Organization*

R327 addressing market need

- **R327 does not contribute to AMR**, supported by unique and multi-layered MoA.
  - **Empowering clinicians** to **confidently** and **quickly administer R327** at first patient presentation.
- Use of R327 may **alleviate the selective pressure on bacteria posed by other antibiotics** and allow them to regain efficacy.

Physician perspectives on R327

"We have so few options when patients have difficult pathogens. This agent would be great to come into play for them." – ID KOL

"This may start off being used in resistant patients, but if it is really compelling, of course physicians will use it for more people." – Pulm. KOL

"If a patient has M. abscessus, they're fortunate if they get any improvement, and there's sometimes potentially permanent damage."
– Pulm. KOL

MDR: Multidrug Resistant; ROA: Route of Administration; IV: Intravenous; MOA: Mechanism of Action; KOL: Key Opinion Leaders. Source: Physician Interviews; Clearview Analysis.

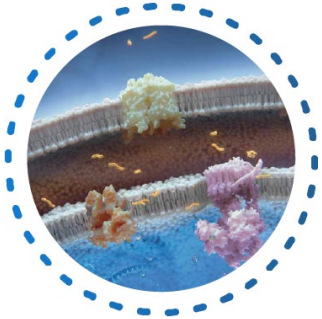
Independent Study Undertaken on R327 MoA[1]

By Leading Experts in Bacterial MoA Analysis

Stage 1

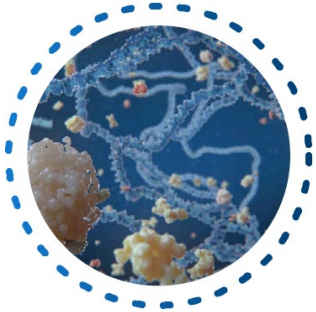
R327 permeabilizes cell membrane and enters the cell

Stage 2



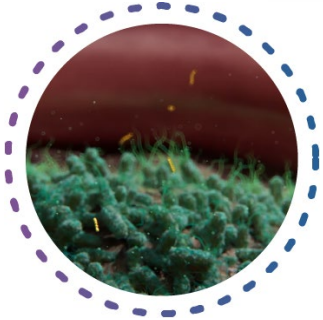
R327 interrupts bacterial cellular energetics via ATP Synthesis

Stage 3



Cellular division & non-dividing cell functions are disrupted

Stage 4



R327 is rapidly and irreversibly bactericidal

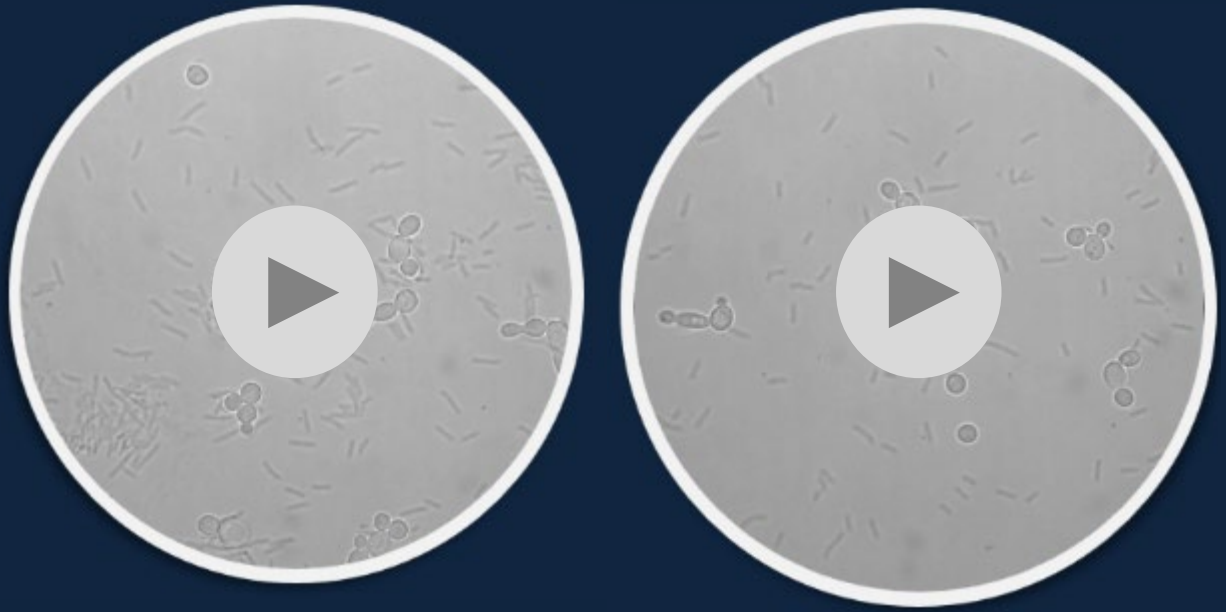
recce.com.au

1 – Dilizia, M., Tsunemoto, H., Quach, D. et al. Elucidating the Mechanism of Action of Novel Polymer-based Synthetic Anti-infective Compound RECCE 327 - Abstract

RECCE® 327 Activity Against *Escherichia coli*

- *E. coli* grows fast. Eukaryotic cells healthy and not affected.
- R327 at 3,000 ppm shown to be highly effective against *E. coli* without affecting growing, healthy eukaryotic cells.
- R327 rapidly and irreversibly shuts down the ATP in *E. coli*, not allowing it to divide and grow.

Without R327 ***R327 (3,000 ppm)***

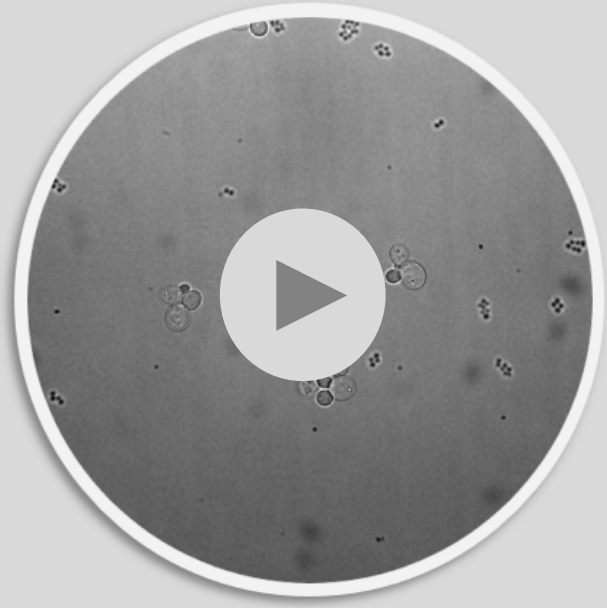


eukaryotic cells ***E. coli***

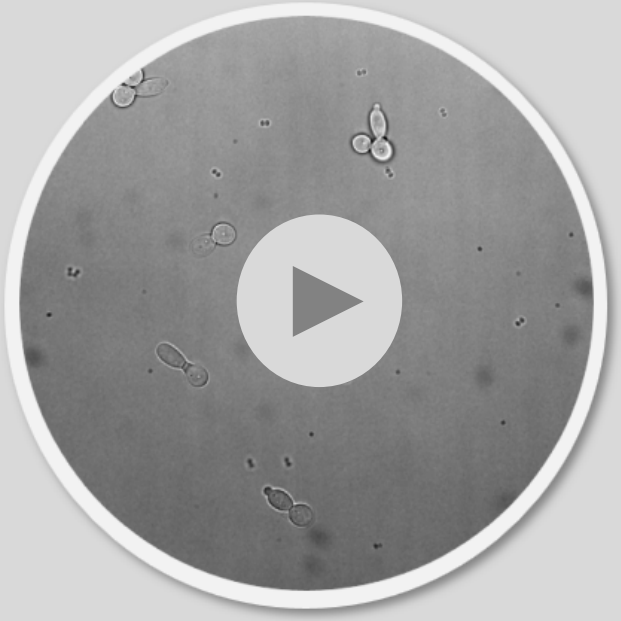
RECCE® 327 Activity Against *Staphylococcus aureus*

- *S. aureus* bacterial growth slower than *E. coli,* not affecting eukaryotic cells.
- **R327 at 2,300 ppm** shows to be highly effective against *S. aureus* without affecting growing, healthy eukaryotic cells.
- **R327 rapidly and irreversibly shuts down the ATP in *S. aureus***, not allowing it to divide and grow.

Without R327



R327 (2,300 ppm)



eukaryotic cells ***S. aureus***

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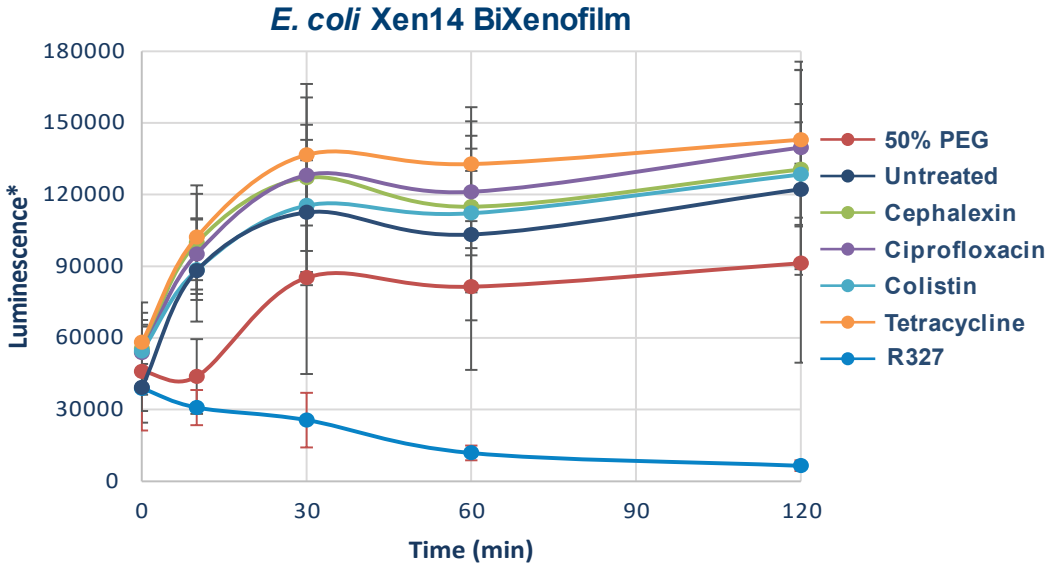
R327 faster acting than existing antibiotics – no prolonged exposure needed



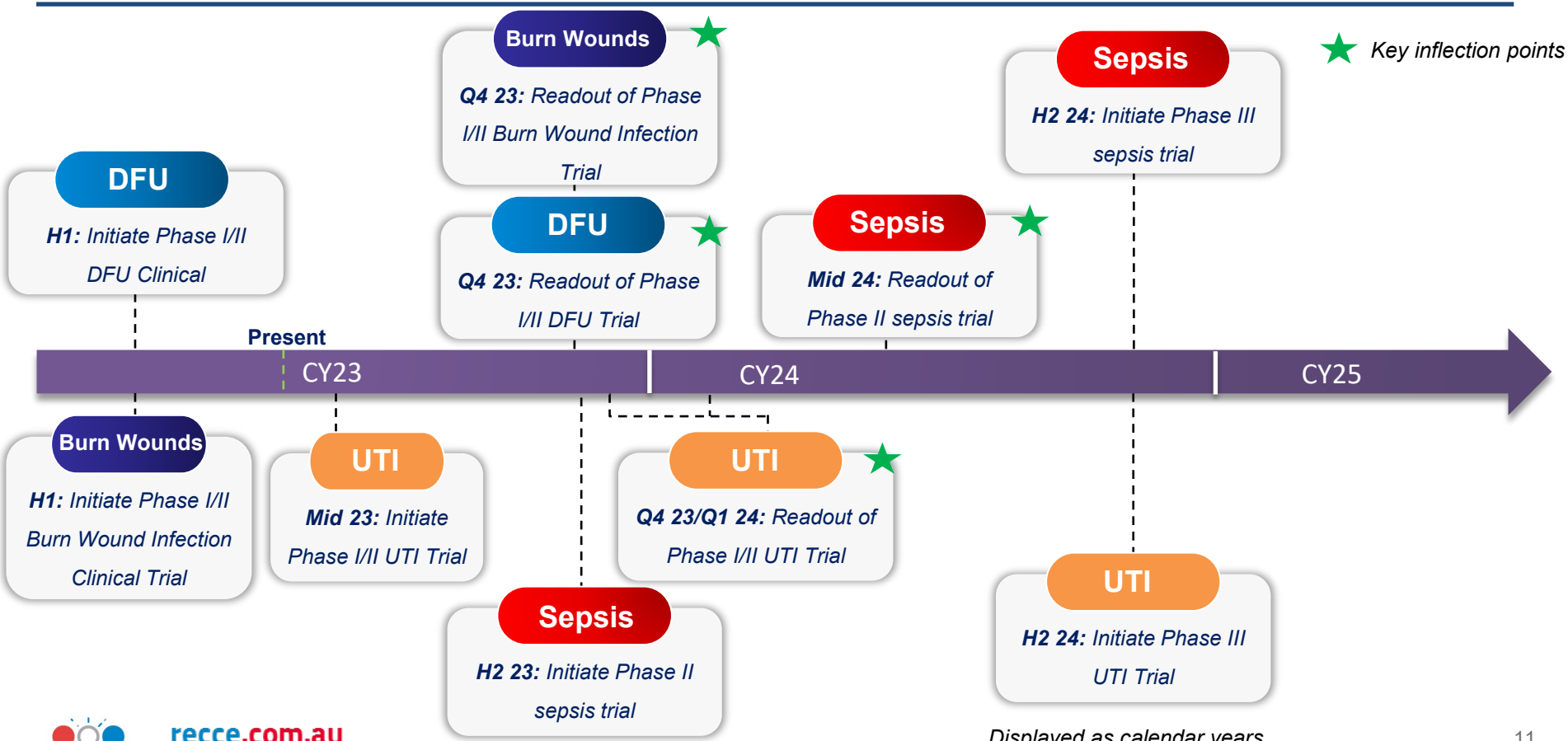
- **R327 kills pathogenic bacteria at a faster rate**.
- **R327 designed to work faster** than all existing antibiotics, reinforced by MoA work undertaken by experts in their field.

> ***"R327 kills bacteria** in conditions where other antibiotics are ineffective."*
>
> *- Marc Sharp, PhD, Chief Scientific Officer, Linnaeus Bioscience*

R327 is faster-acting against bacteria than other antibiotics – works quickly, without prolonged cellular exposure times required of other antibiotics (extended exposures commonly associated with systemic toxicity).

**Xen14 (a reduction in luminescence correlates with decrease in cell viability)*
**All compounds used at 2X Minimum Inhibitory Concentration (MIC)*

Multiple Upcoming Clinical Milestones



Displayed as calendar years
Milestones are displayed for illustrative purposes only

Sepsis – it's a big problem!

48.9 million incident cases of **sepsis** recorded worldwide[1]

11 million sepsis-related deaths recorded[2]

One in three patients who **die** in hospital have sepsis[3]

What is Sepsis?

Sepsis is a life-threatening inflammatory response to infection that has spread in the body.

Economic Impact

Is the **most expensive condition to treat** in the last 8 years[5].

Double the average cost per stay across all other conditions[5].

Social Impact

Kills more people in the US than **prostate**, **breast cancer** and **HIV/AIDS** combined[4].

Currently no drug therapies specifically for the treatment of sepsis[6].

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1,2,3 – The Lancet
4 – BioMed Central
5 – University of Texas
6 – International Medicine Journal RACP

Recently Approved Antibiotics – Benchmark for Pricing

Anticipated Pricing Benchmarks[1]

- Though Xigris (activated protein C) was pulled from the market in 2011, its pricing represents a potential premium benchmark for a novel sepsis agent
- Fetroja, a recently approved agent for UTIs, was granted an NTAP by CMS with a maximum payment of ~$8K for a patient treated with the agent
- Arikayce (Amikacin) is an aminoglycoside antibiotic. Used to treat certain kinds of bacterial infections in the lungs, with a potential pricing as low as USD $27K

Physician Perspectives

"A novel molecule demonstrating convincing efficacy may get pricing up to $15 – 20 K like Xigris." – Payer

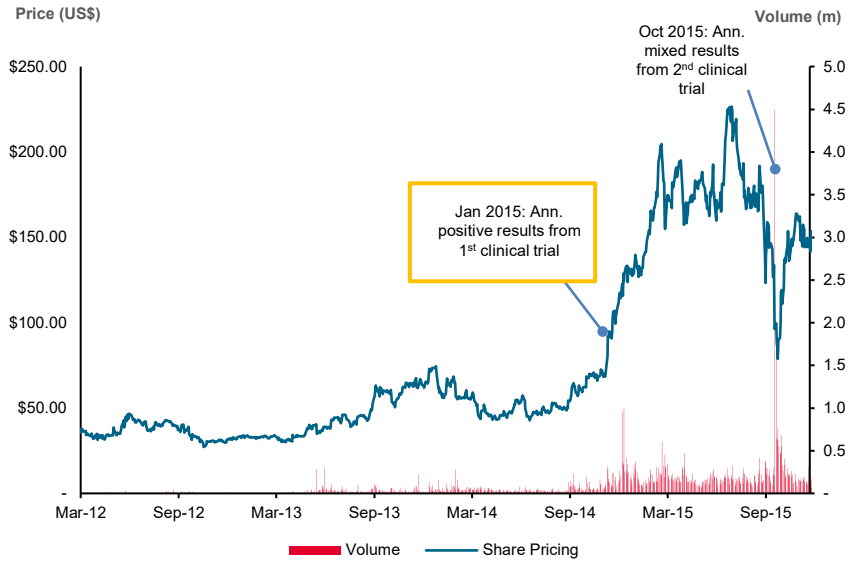
"Cost savings are important here; even if we don't see that many sepsis patients annually, the individual patient cost is very high." – Payer

[1] Antibiotic prices assume an average 7 – 10 day treatment course, although duration of antibiotic therapy in sepsis is not well characterized; [2] DRG codes are differentiated based on whether patient is ventilated for >96 hours and designation of major complications/comorbidities. HEOR: Health Economics and Outcomes Research; NTAP: New Technology Add-on Payment. Source: Busch. The Journal of Infectious Diseases. 2020; Paoli. *Crit Care Med.* 2018; CMS; Payer Interviews; ClearView Analysis.

Successfully Completing a Clinical Trial Phase Can Lead to Significant Share Price Increase

Case studies: Other antibiotic companies

- **Positive top line results** from a global, pivotal Phase III clinical trial of solithromycin oral capsules (Solitaire-Oral) **in the treatment of patients with community acquired bacterial pneumonia.**
- **Solithromycin met the primary and secondary objectives** of non-inferiority compared to moxifloxacin.



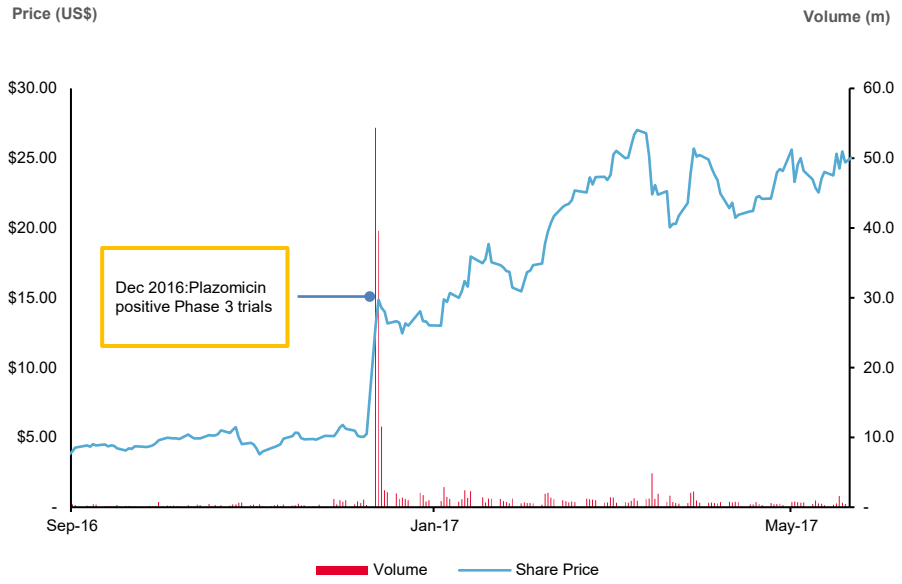
https://www.globenewswire.com/en/news-release/2015/01/04/694774/26624/en/Cempra-Announces-Positive-Topline-Phase-3-Clinical-Results-for-Oral-Solithromycin-in-the-Treatment-of-Community-Acquired-Bacterial-Pneumonia.html

Successfully Completing a Clinical Trial Phase Can Lead to Significant Share Price Increase

Case studies: Other antibiotic companies

- In December 2016, Achaogen announces **positive results in Phase III cUTI and CRE clinical trials of Plazomicin**.
- EPIC registration **trial successfully achieved FDA primary endpoints in patients with cUTI**.
- Achaogen planned to submit a new drug application (NDA), which will include EPIC and CARE data, to FDA in second half of 2017.

ACHAOGEN



https://www.reuters.com/article/idCNASC09MUW

Large strategics are also paying attention

Case studies: Partnering antibiotic assets creates value

US$66 million upfront and Up to US$525 million in potential milestones plus royalties

Exclusive licence agreement for tebipenem HBr

SPERO THERAPEUTICS

September 2022

GSK and Spero Therapeutics announce exclusive licence agreement for late-stage antibiotic that may treat complicated UTIs

Spero will start a new Phase III clinical trial in 2023, following encouraging US FDA regulatory feedback on the proposed clinical trial design

First oral carbapenem antibiotic to potentially treat complicated **urinary tract infections** (cUTI), including pyelonephritis, caused by certain bacteria

Many recent deals within the anti-infectives space have seen larger companies with an entrenched presence acquiring smaller Biotech's

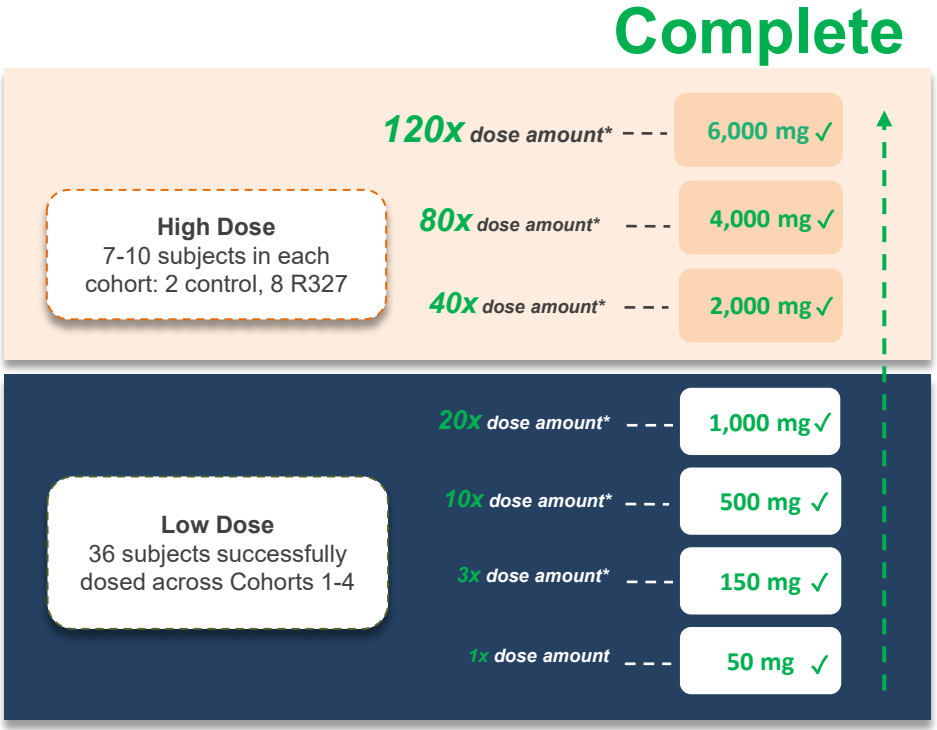
Key Recent Deals in Infectious Disease

Companies Involved	Deal Details	Total Value	Key Takeaways
Pfizer / amplyx	• **Deal Date:** April 2021 • **Deal Type:** Acquisition of Company	Undisclosed	• Amplyx was developing therapies for patients with compromised immune systems • Antifungal lead compound, Fosmanogepix, in Phase 2 clinical trials
SANDOZ A Novartis Division / gsk	• **Deal Date:** February 2021 • **Deal Type:** Acquisition of Brands	Up to $500 M	• Sandoz acquired GSK's cephalosporin antibiotics business including global rights to Zinnat, Zinacef, and Fortum • $350 M upfront and up to $150 M in milestones
La Jolla Pharmaceutical / TETRAPHASE PHARMACEUTICALS	• **Deal Date:** July 2020 • **Deal Type:** Acquisition of Company	Up to $75 M	• $43 M upfront and up to $32 M in milestones contingent on net sales of Xerava • Tetraphase terminated previous agreement with Melinta given La Jolla's stronger offer
Roche / FORGE Therapeutics	• **Deal Date:** March 2020 • **Deal Type:** Research Collaboration and Licensing	Up to $190.5 M	• Roche licensed Forge's FG-LpxC LUNG, an antibiotic for treatment of lung infections attributed to antibiotic-resistant Gram-negative bacteria

Source: Global Data; Press Releases; ClearView Analysis

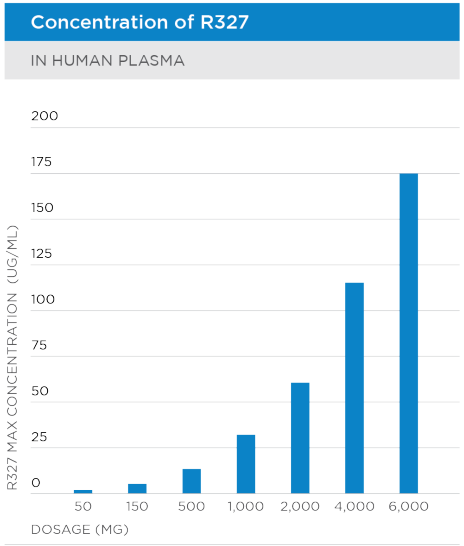
Phase I Human Clinical Trial

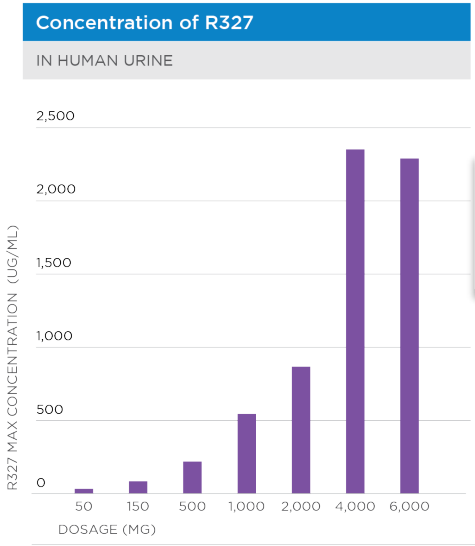
- **Study to assess IV infusion of RECCE® 327 in healthy male subjects as a single ascending dose.**
- Randomized, double-blind, placebo-controlled, safety, tolerability and pharmacokinetics study.
- Single dose of a 1-hour via IV infusion at a uniform rate in hospital setting.
- Primary endpoint: vital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



*Dose increase fold based off 50mg

Reason for Optimism in Treating UTI/Sepsis





Dr Alan Dunton's Clinical Update

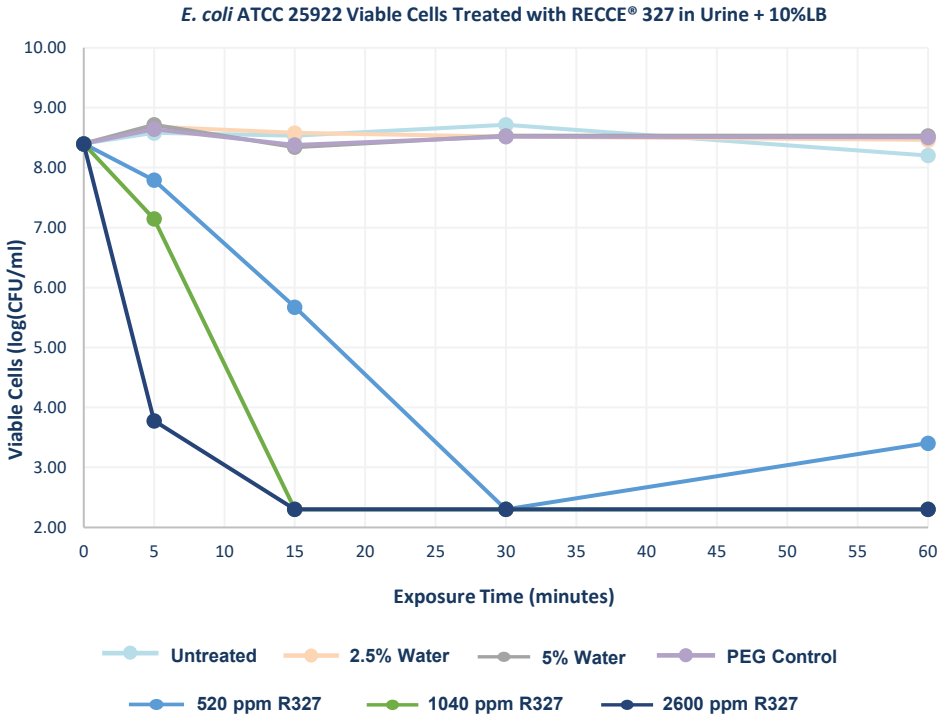
Concentration of R327 in Urine Compared to Plasma

Ratio Urine/Plasma -
15x
13x
15x
17x
14x
20x
13x

In over 60 healthy subjects

- **R327 primary route of elimination** appears to be through the kidney to the ureters and bladder.
- **High concentrations of R327** noted in the urine of Phase I healthy subjects.
- **Insight consistent** with pre-clinical *in-vivo* kidney and UTI bacterial infection studies.
- **Opportunities for therapeutic in array of UTIs (uncomplicated UTI - single dose, complicated UTI, recurrent UTI, treatment resistant etc).**
- Suggests **broader anti-infective treatment model** in pre-sepsis.

RECCE® 327 Kills Quickly in the Urine



- **R327 in the presence of human urine was able to have a fast (near minutes effect against *E. coli* and irreversible**
- **Bacteria could not be 'washed out' and regrown**
- R327 capability starting from comparatively low concentrations
- Achieved 6-log reduction in viable cell count

Understanding logs (example of a small colony of 1 million MRSA bacteria)*
A 1-log kill reduces the colony to 100,000 MRSA bacteria after a 90% reduction
A 2-log kill reduces the colony to 10,000 bacteria after a 99% reduction
A 3-log kill reduces the colony to 1,000 bacteria after a 99.9% reduction
A 4-log kill reduces the colony to 100 bacteria after a 99.99% reduction
A 5-log kill reduces the colony to 10 bacteria after a 99.999% reduction
A 6-log kill reduces the colony to 1 MRSA bacterium after a 99.9999% reduction

*https://halosil.com/what-are-logs-and-why-do-they-matter-in-preventing-infections/

Patents

Four families across all major markets

Filed	Patent Family 1	Expiry	Patent Family 2	Expiry	Patent Family 3	Expiry
Australia	✓	2028	✓	2037	**Accepted**	2037
USA	✓	2029	✓	2037	✓	2037
Europe	✓	2028	✓	2037	✓	2037
Germany	✓	2028	✓	2037	✓	2037
Spain	✓	2028	✓	2037	✓	2037
France	✓	2029	✓	2037	✓	2037
UK	✓	2028	✓	2037	✓	2037
Italy	✓	2028	✓	2037	✓	2037
Sweden	✓	2028	✓	2037	✓	2037
Japan	✓	2028	✓	2037	✓	2037
China	✓	2028	Pending	2037	✓	2037
HK	Pending	2028	Pending	2037	✓	2037

Family 1 group relates to the Company's Unique and Highly Economical Manufacturing Process and use of the Polymer in Treatment of Diseases.

Family 2 relates to the Method of Manufacture, Administration and Application to Treat a Broad Range of Common Human Infections.

Family 3 relates to a Method of Treatment of a Broad Range of Viral Infections, particularly Parenteral Viral Infection.

Recce's patent portfolio contains over 40 patents and patent applications in the world's major markets.

Country	Title	Case_Status	Grant_Date	Applicant	Family
Australia	ANTI-MICROBIAL POLYMERS AND THEIR COMPOSITIONS	Granted	25/08/2011	Recce Pharmaceuticals Ltd	Family 1
China	ANTI-MICROBIAL POLYMERS AND THEIR COMPOSITIONS	Granted	25/11/2015	Recce Pharmaceuticals Ltd	Family 1
France	ANTI-MICROBIAL POLYMERS AND THEIR COMPOSITIONS	Granted	7/10/2015	Recce Pharmaceuticals Ltd	Family 1
Germany	ANTI-MICROBIAL POLYMERS AND THEIR COMPOSITIONS	Granted	7/10/2015	Recce Pharmaceuticals Ltd	Family 1
Italy	ANTI-MICROBIAL POLYMERS AND THEIR COMPOSITIONS	Granted	7/10/2015	Recce Pharmaceuticals Ltd	Family 1
Japan	ANTI-MICROBIAL POLYMERS AND THEIR COMPOSITIONS	Granted	3/10/2014	Recce Pharmaceuticals Ltd	Family 1
Spain	ANTI-MICROBIAL POLYMERS AND THEIR COMPOSITIONS	Granted	7/10/2015	Recce Pharmaceuticals Ltd	Family 1
Sweden	ANTI-MICROBIAL POLYMERS AND THEIR COMPOSITIONS	Granted	7/10/2015	Recce Pharmaceuticals Ltd	Family 1
UK	ANTI-MICROBIAL POLYMERS AND THEIR COMPOSITIONS	Granted	7/10/2015	Recce Pharmaceuticals Ltd	Family 1
USA	ANTI-MICROBIAL POLYMERS AND THEIR COMPOSITIONS	Granted	1/09/2015	Recce Pharmaceuticals Ltd	Family 1
Australia	COPOLYMER AND METHOD FOR TREATMENT OF BACTERIAL INFECTION	Granted	8/11/2018	Recce Pharmaceuticals Ltd	Family 2
China	COPOLYMER AND METHOD FOR TREATMENT OF BACTERIAL INFECTION	Response Lodged		Recce Pharmaceuticals Ltd	Family 2
France	COPOLYMER AND METHOD FOR TREATMENT OF BACTERIAL INFECTION	Granted	28/08/2019	Recce Pharmaceuticals Ltd	Family 2
Germany	COPOLYMER AND METHOD FOR TREATMENT OF BACTERIAL INFECTION	Granted	28/08/2019	Recce Pharmaceuticals Ltd	Family 2
Italy	COPOLYMER AND METHOD FOR TREATMENT OF BACTERIAL INFECTION	Granted	28/08/2019	Recce Pharmaceuticals Ltd	Family 2
Japan	COPOLYMER AND METHOD FOR TREATMENT OF BACTERIAL INFECTION	Granted	25/10/2019	Recce Pharmaceuticals Ltd	Family 2
Spain	COPOLYMER AND METHOD FOR TREATMENT OF BACTERIAL INFECTION	Granted	28/08/2019	Recce Pharmaceuticals Ltd	Family 2
Sweden	COPOLYMER AND METHOD FOR TREATMENT OF BACTERIAL INFECTION	Granted	28/08/2019	Recce Pharmaceuticals Ltd	Family 2
UK	COPOLYMER AND METHOD FOR TREATMENT OF BACTERIAL INFECTION	Granted	28/08/2019	Recce Pharmaceuticals Ltd	Family 2
USA	COPOLYMER AND METHOD FOR TREATMENT OF BACTERIAL INFECTION	Granted	12/03/2019	Recce Pharmaceuticals Ltd	Family 2
Australia	ANTI-VIRUS AGENT AND METHOD FOR TREATMENT OF VIRAL INFECTION	Accepted		Recce Pharmaceuticals Ltd	Family 3
China	ANTI-VIRUS AGENT AND METHOD FOR TREATMENT OF VIRAL INFECTION	Granted	22/06/2021	Recce Pharmaceuticals Ltd	Family 3
France	ANTI-VIRUS AGENT AND METHOD FOR TREATMENT OF VIRAL INFECTION	Granted	21/04/2021	Recce Pharmaceuticals Ltd	Family 3
Germany	ANTI-VIRUS AGENT AND METHOD FOR TREATMENT OF VIRAL INFECTION	Granted	21/04/2021	Recce Pharmaceuticals Ltd	Family 3
Hong Kong	ANTI-VIRUS AGENT AND METHOD FOR TREATMENT OF VIRAL INFECTION	Granted	25/02/2022	Recce Pharmaceuticals Ltd	Family 3
Italy	ANTI-VIRUS AGENT AND METHOD FOR TREATMENT OF VIRAL INFECTION	Granted	21/04/2021	Recce Pharmaceuticals Ltd	Family 3
Japan	ANTI-VIRUS AGENT AND METHOD FOR TREATMENT OF VIRAL INFECTION	Granted	18/12/2020	Recce Pharmaceuticals Ltd	Family 3
Spain	ANTI-VIRUS AGENT AND METHOD FOR TREATMENT OF VIRAL INFECTION	Granted	21/04/2021	Recce Pharmaceuticals Ltd	Family 3
Sweden	ANTI-VIRUS AGENT AND METHOD FOR TREATMENT OF VIRAL INFECTION	Granted	21/04/2021	Recce Pharmaceuticals Ltd	Family 3
United Kingdom	ANTI-VIRUS AGENT AND METHOD FOR TREATMENT OF VIRAL INFECTION	Granted	21/04/2021	Recce Pharmaceuticals Ltd	Family 3
USA	ANTI-VIRUS AGENT AND METHOD FOR TREATMENT OF VIRAL INFECTION	Granted	29/06/2021	Recce Pharmaceuticals Ltd	Family 3
USA	ANTI-VIRUS AGENT AND METHOD FOR TREATMENT OF VIRAL INFECTION	Filed		Recce Pharmaceuticals Ltd	Family 3

In-house Manufacturing Capabilities

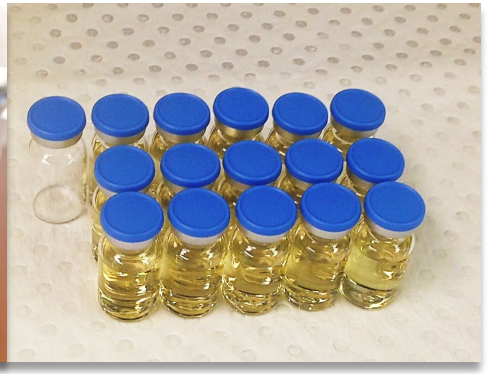
Manufacturing facility in Sydney's Macquarie Park

- Raw **materials plentiful and cheap** – few $/Kg
- **No expensive waste** – 99.9% product yield

- Automated **manufacture process taking approx. 1 hour**
- **500 doses** per fully automated run

- Quality and Quantity demonstrated capability to support present and future human clinical trials.

- Facility built to pharmaceutical specification.
- Packaging and labelling to international standards

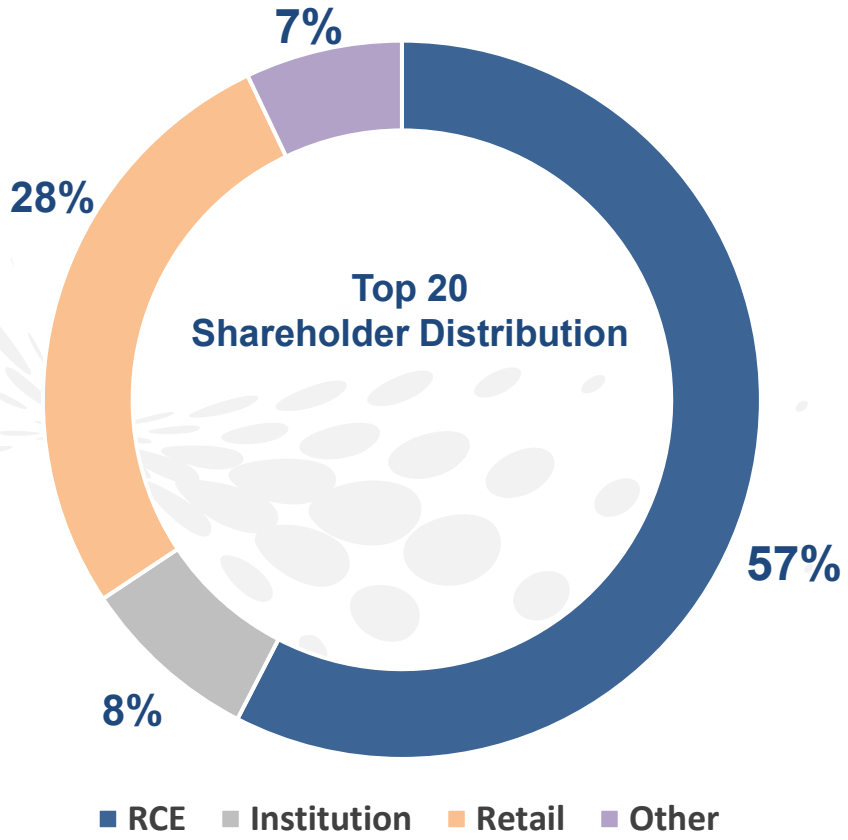


Recce Pharmaceuticals Ltd – Capital Structure

Snapshot

Tickers	ASX:**RCE**, FSE:**R9Q**
Market Cap (approx.) Priced at AUD $0.60/share	**AUD $107 million**
Cash and deposits* 30 January 2023	**AUD $8.05 million****
Outstanding shares	**178.25 million**
Average daily volume 3 months	**57.6k**
Debt	**Nil**

***Includes cash balance of $A1.84m and A$6.21m from R&D rebate*



Thank you

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