

CEO Presentation

ASX:RCE | FSE:R9Q

November 2023

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About Recce Pharmaceuticals Ltd

- Recce Pharmaceuticals Ltd (ASX: RCE, FSE: R9Q) is developing a new class of Synthetic Anti-Infectives, protected by Composition of Matter Patent
- Australian clinical-stage biotech company, with a United States presence
- **Strong pre-clinical data package** demonstrating **high bactericidal activity** combined with **very good safety** at expected human therapeutic range
- **Qualified Infectious Disease Product designation**
 - 10 years market exclusivity plus fast track approval*
- RECCE® 327 (main product candidate) has been included on **The Pew Charitable Trusts Global New Antibiotics in Development Pipeline** as the world's only synthetic polymer, sepsis drug candidate in development
- Multiple clinical indications and formulations in Phase I and II addressing unmet medical needs



Board and 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 Nighthawk Biosciences (NYSE: HHWK). With extensive experience in the international commercialisation of pharmaceutical technologies, **Dr Prendergast has been responsible for the approval of three new drug applications.**



James Graham – Managing Director & Chief Executive Officer

BCom (Entrepreneurship), GAICD

Six years as former Executive Director and extensive experience in marketing, business development and commercialisation of early-stage technologies with global potential. Mr Graham has served on Recce's Board of Directors for six years and has invested in almost every capital raise to date with a focus on expanding Recce's commercial opportunities and clinical initiatives.

Dr Alan Dunton – Chief Medical Advisor & Non-Executive Director

BSc (BioChem) Hons, M.D. (NYU)

US based, Director of Palatin Technologies. Over three decades of senior pharmaceutical experience incl. President and MD of Janssen Research Foundation (Johnson & Johnson). **Dr Dunton has advanced a number of blockbuster antibiotics** through regulatory review and commercialisation at Fortune 500 companies including Roche. **Dr Dunton has been responsible for the approval of approximately 20 New Drug Applications;** an amalgamation of prescription and OTC products.



Michele Dilizia – Executive Director & Chief Scientific Officer

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

Co-inventor and qualified medical scientist with a specialisation in medical microbiology and regulatory affairs. Ms Dilizia successfully co-led the research and development of Recce's suite of anti-infective compounds, resulting in a portfolio of granted patents across the globe, including a Qualified Infectious Disease Product designation with the U.S. FDA.

Dr Justin Ward – Executive Director & Principal Quality Chemist

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

A quality control expert who has worked with leading pharmaceutical companies. He previously held a technical role with Pfizer, involving providing data for the regulatory submissions to the FDA and TGA. Dr Ward is bringing Recce's research and development, and manufacturing up to US FDA requirements



Alistair McKeough – Non-Executive Director

Alistair is a qualified lawyer and specialises in complex commercial matters that require careful and strategic planning. Mr McKeough has extensive experience advising ASX-listed companies and their directors and is a member of the University of New South Wales Law Advisory Council.

Since our last AGM

We've announced and achieved the following:

- ✓ Received HREC Approval to start Phase I/II DFI Study
- ✓ Anti-Infective Research Unit Established at Murdoch Children's
- ✓ Australian Patent to be Granted for RECCE Anti-infectives
- ✓ Presented at LifeSci Corporate Access Event during the JP Morgan Health Care Conference
- ✓ Received AUD \$6.21m from R&D Rebate Payments
- ✓ RECCE trademark Registered – Hong Kong
- ✓ Selected CMAX for Phase I/II UTI clinical Trial
- ✓ Corporate Presentations in Sydney and London for the Wholesale Investor Emergence Conference Series
- ✓ Received a further AUD \$973k R&D advance
- ✓ New Australian Family 4 Patent to be granted for RECCE anti-infectives
- ✓ RECCE trademark Registered – Israel
- ✓ HREC Approval to start Phase I/II UTI/Urosepsis clinical trial
- ✓ WA Government Sponsorship for BIO Korea 2023
- ✓ Appointed Outpatient Nurses to Phase I/II DFI Clinical Trial
- ✓ HREC Approval for Phase I/II UTI/Urosepsis Trial Site Expansion (Scientia)
- ✓ First Cohort Dosed in Faster Infusion Phase I/II UTI/Urosepsis Study
- ✓ Received an additional AUD \$801k R&D Rebate
- ✓ Phase I Clinical Trial Data Complete Review
- ✓ Scientia Doses Ahead of Schedule in Phase I/II UTI/Urosepsis Trial
- ✓ Abstract & Poster Presentation at US Military Symposium
- ✓ Scientia Completes Cohort Dosing in Phase I/II UTI/Urosepsis Trial
- ✓ Bonus Canadian R&D Rebate Received
- ✓ Australian Patent Granted for RECCE Anti-Infectives
- ✓ Positive Patients Update – Special Access Scheme
- ✓ Phase I/II Burn Wound Infection Trial Stage 1 Complete



recce.com.au

39 announcements

- ✓ Patients Dosed in R327 DFI Trial
- ✓ Safety Committee Approved Dose of 3,000mg faster infusion rate at 30 mins
- ✓ Additional Patients dosed in Special Access Scheme
- ✓ RECCE trademark Registered – Vietnam
- ✓ Delivered Opening R&D Address at World AMR Congress
- ✓ Placement and Entitlement Offer – Capital Raise
- ✓ FIL becomes Substantial Holder
- ✓ R327 safe and well tolerated in male and female subjects at a faster infusion rate of 30 minutes of 3,000mg
- ✓ Entitlement Offer – Announcement of Capital Raise Results
- ✓ Recce Pharmaceuticals Annual Report 2023
- ✓ Placement of Entitlement Offer Shortfall
- ✓ Safety Committee Approves Dose Faster Infusion rate of 15-minutes of 3,000mg
- ✓ Presented at the Ord Minnett Health Care Forum
- ✓ Subjects Dosed Over 15 mins in UTI/Urosepsis Clinical Trial

Breakdown by Category – 2023 Announcements

Clinical	18	46%
Operational	13	33%
Financial	8	21%

Breakdown by Category – 2022 Announcements

Clinical	15	71%
Operational	5	5%
Financial	1	24%

2022 Corporate Goals



New Clinical Data Sets

Phase I Intravenous Study data sets to be released



Global Strategy - Partnerships

Continued engagement in partnership opportunities with both domestic and international organisations



Strengthen Intellectual Property

Including internationally recognised drug designations



Peer-Reviewed Publications – Ongoing Recognition of R327's Unique Mechanism of Action unique with clinical context



ESCMI

EUROPEAN SOCIETY
OF CLINICAL MICROBIOLOGY
AND INFECTIOUS DISEASES



AMERICAN
SOCIETY FOR
MICROBIOLOGY

MHSRS
Military Health System
Research Symposium



Publication	Location	Title
Abstract and Poster Presentation	Military Health System Research Symposium	R327: A Novel Synthetic Anti-Infective for the Treatment of AMR Bacterial Sepsis Infections
Abstract	ESCMI/ASM	R327 Demonstrates Bactericidal Activity Against Several Microbial Species

2023/2024 Corporate Goals



Data Review and Completion of Clinical Trials

Successfully streamline and accelerate current clinical trial processes in chosen indications and routes of administration



Government/Private Enterprise Partnerships

Funding, research partnerships, licensing, grant submissions, military areas of interest



Submit Investigational New Drug (IND) application



Build Out Presence in the USA

Further expand capabilities in USA supporting FDA strategy

Company Overview

Recce Pharmaceuticals Ltd is a clinical-stage biotech company with a new class of novel synthetic anti-infectives

Capital Structure – 6th November 2023

ASX & FSE Code	RCE, R9Q
Share Price	AUD \$0.43
3-Month Average Volume	253.4k
Shares on Issue	203 million
Unlisted Options (Avg \$1.54)	13.9 million
Market Capitalisation	AUD \$87 million
Cash at Bank	AUD \$8.36 million*
Top 20 Shareholders	51%
Debt	Nil

**Before 43.5% R&D Rebate submitted - net benefit from anticipated receipt during present quarter*



Multiple near-term clinical readouts



Multiple clinical indications and formulations in Phase I and Phase II addressing unmet medical needs: **Sepsis, UTI, Burn Wounds and Diabetic Foot Ulcer Infections**

RCE Share Price and Volume Chart – 12 Months



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%



Proprietary **first-in-class, broad-spectrum anti-infectives** against bacteria

Successful Capital Raise – AUD \$11 million

- The Company announced it successfully completed a strongly supported raise of **AUD \$11 million** (before costs) through a placement to institutional, sophisticated and professional investors completed on 18 September 2023 and an Entitlement Offer which completed on 29 September 2023.
- **James Graham, CEO, took up his full entitlement, investing a further AUD \$102.7k into the Company.**
- Directors of the Company took a portion of the Shortfall (AUD \$0.3m), representing approximately 250,000 shares (AUD \$110k).
- **Recce received major institutional support in capital raise from FIL (Fidelity) Limited**
- Funds raised will be used to fund various clinical trials, build out RCE's infectious disease portfolio, geographical expansion and general working capital.

Fidelity International Ltd (FIL) are now a substantial shareholder of Recce Pharmaceuticals Ltd owning 7.69%

Capital Raise Snapshot

Total Raised	AUD \$11m
Placement	AUD \$8.0m
Entitlement Offer	AUD \$3.0m
Director Shortfall Participation	250,000 Shares (AUD \$110k)
FIL Limited Increased Holding	7.69%
New Shares Issued	6.171m

Top 20 Shareholders Movements since last AGM – Increased Support

Position	Holder/Group Name	6-Nov-23		Holding Movement	Total % Increase Since Last AGM
		Balance	Issued Capital (%) 6 Nov 23		
1	G & O Melrose	37,028,311	18.20%	-	-
2	HSBC Custody Nominees (Australia) Limited	13,348,988	6.56%	6,844,408	105.22%
3	M Rogers and A Veliss	8,500,000	4.18%	3,500,000	70.00%
4	Mr James Graham	7,593,932	3.73%	1,562,000	25.90%
5	Acuity Capital Investment Management Pty Ltd <Acuity Capital Holdings A/C>	4,500,000	2.21%	-	-
6	Ms Michele Keryn Dilizia	3,543,485	1.74%	-	-
7	Acewood Investments Pty Ltd <Chivers Super Fund A/C>	3,307,101	1.63%	122,485	3.85%
8	Mr John James Liddelow <John Liddelow A/C>	3,040,000	1.49%	610,000	25.10%
9	Pejay Pty Limited	3,000,000	1.47%	750,000	33.33%
10	Citicorp Nominees Pty Limited	2,675,183	1.31%	1,639,798	158.38%
11	BNP Paribas Nominees Pty Ltd ACF Clearstream	2,637,254	1.30%	1,437,859	119.88%
12	Querion Pty Ltd	2,100,000	1.03%	-	-
13	Haultrans Management Pty Limited <Successful Super Fund A/C>	1,870,000	0.92%	1,410,000	306.52%
14	BNP Paribas Noms Pty Ltd	1,734,359	0.85%	95,908	5.85%
15	LDU Pty Ltd	1,484,882	0.73%	-1,739,510	-53.95%
16	Mr Michael Noel Aarons & Mrs Mami Aarons <The Aarons Superfund A/C>	1,437,498	0.71%	-	-
17	Mark David Swinn	1,314,720	0.65%	97,718	8.03%
18	BNPP Noms Pty Ltd HUB24 Custodial Serv Ltd	1,273,198	0.63%	142,032	12.56%
19	Mr Nikolai Shirobokov & Mrs Svetlana Shirobokov	1,260,036	0.62%	148,062	13.32%
20	Mr Peter McCray	1,083,661	0.53%	53,500	5.19%
Total Top 20 Holder Increase		102,730,233	50.49%	17,091,000	-

Top 20 Shareholding as of 2022 – 48.74%

Top 20 Shareholding as of 2023 – 50.49% (increase 1.75%)

Platform Technology

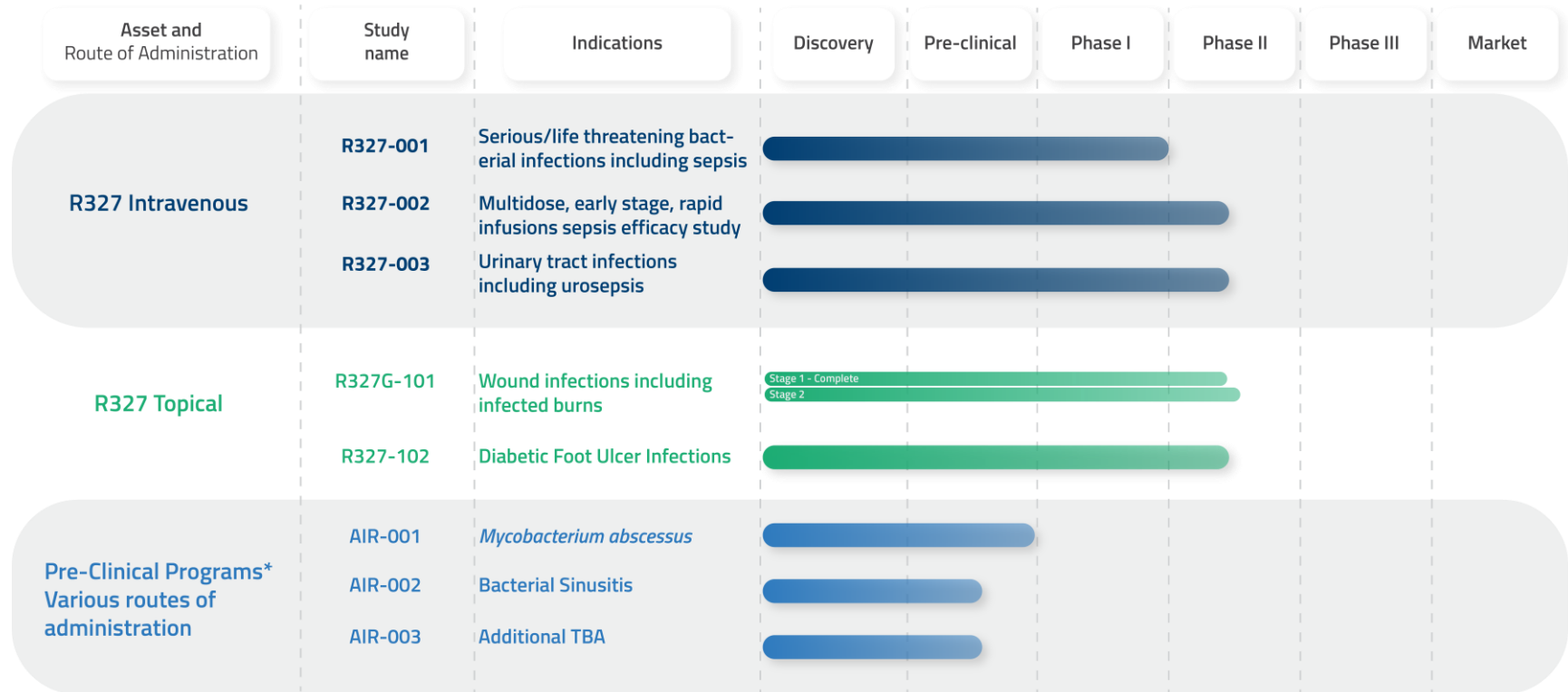
Recce's products will treat systemic and local infections caused by ESKAPE pathogens, other resistant organisms or when the etiology of the infection is unknown

- Very broad-spectrum coverage of bacteria with **no signs of resistance**
- **Extremely rapid onset of effect** – measured in minutes as compared to hours for typical antibiotics
- **Multiple formulations available** – intravenous, topical liquid, topical gel and aerosol for inhalation or intranasal
- **Manufacturing** – fast and economical
- Readily available raw materials
- Prolonged stability of product(s)



Strong Pipeline

Over Various Indications and Upcoming Inflection Points



*AIR – Anti infective Research Unit



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Phase I Human Clinical Trial - Complete

- 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.
- In concurrence with the Therapeutic Goods Administration clinical trial regulatory procedures, the recruitment for the study is closed and marked '**Complete**' with no '**Serious Adverse Events**' reported.
- **Safe up to and including 6,000mg using a 1-hour infusion**
 - 60 subjects received R327, 20 subjects received placebo
- Plasma concentrations are linear vs. dose and "predictable"

120x dose amount*	---	6,000 mg ✓
80x dose amount*	---	4,000 mg ✓
60x dose amount*	---	3,000 mg ✓
40x dose amount*	---	2,000 mg ✓

20x dose amount*	---	1,000 mg ✓
10x dose amount*	---	500 mg ✓
3x dose amount*	---	150 mg ✓
1x dose amount	---	50 mg ✓

*Dose increase fold based off 50mg



RECCE® 327 - Intravenous formulation – Phase I

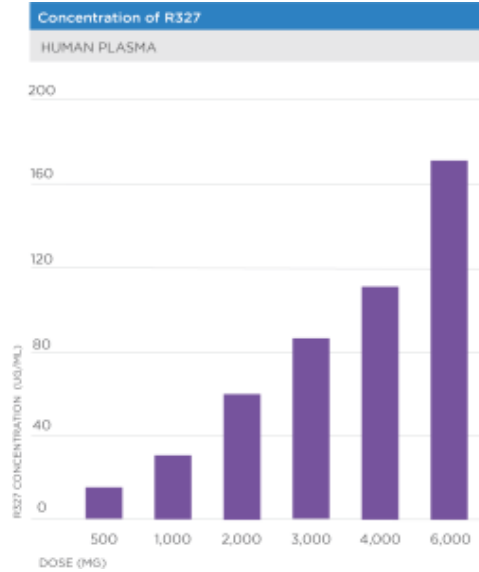
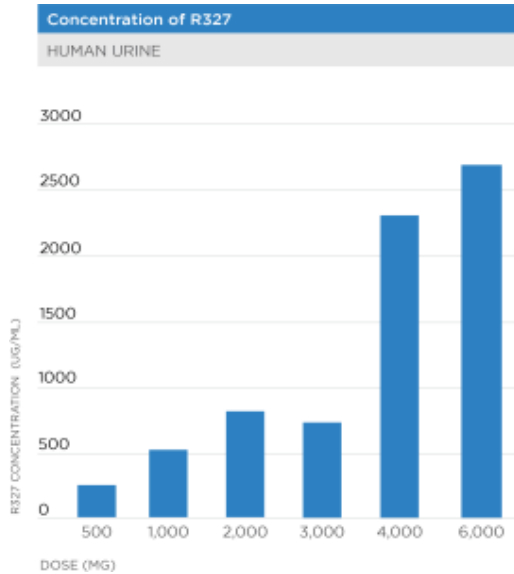


Summary of Results – All Primary Endpoints Achieved

- ✓ No serious adverse events (SAEs) or deaths were reported in this study.
- ✓ No clinically significant changes were noted in any hematology parameter(s) in any cohort during the course of the study.
- ✓ No clinically significant changes were noted in any chemistry parameter(s) in any cohort during the course of the study (Kidney and Liver functions all normal – no change in parameters).
- ✓ All coagulation parameters remained within normal limits or were deemed not clinically significant (Normal blood clotting properties were maintained).
- ✓ No clinically significant changes were noted in any urinalysis parameter(s) in any cohort during the course of the study (i.e. no adverse event/side effect).
- ✓ No clinically significant changes were noted in any vital sign (included systolic blood pressure, diastolic blood pressure, heart rate, respiratory rate, and body temperature) parameter(s) in any cohort during the course of the study.
- ✓ No clinically significant changes were noted in any 12-lead ECG parameter(s) in any subject in any cohort during the course of the study (no cardiac event).
- ✓ No clinically significant changes were noted in any cardiac telemetry parameter(s) in any subject in any cohort during the course of the study (no cardiac abnormalities during continuous heart monitoring whilst under observation).



RECCE® 327 Concentrates Safely in the Urine



Concentration of R327 in
Urine Compared to
Plasma

In over 60 healthy
subjects

Ratio Urine/Plasma -
16x
17x
14x
9x
21x
16x

- **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.

Phase I/II UTI/Urosepsis Rapid Infusion Clinical Trial

- Assessing R327 at faster administration rates (<1 hour)
- Trial aimed at positioning **R327 as first patient presentation** 'fast-infusion' **designed to stop any bacterial infection** in its tracks in any medical setting
- **Male and female subjects dosed**
- Results from this trial will pave the way for **R327 as a potential first-line treatment for patients suffering from UTI/Urosepsis**
- **Qualified Infectious Disease Product designation**
 - Awarded by the US FDA in 2017 for R327 bacteraemia (broad-spectrum bacterial sepsis).

*UTI's are responsible for about 30% of all
sepsis infections, defined as '**Urosepsis**'*



High Dose – 15 minutes

Cohort 4
TBD mg (?)



Cohort 3
3,000mg



✓ *Dosing commenced*

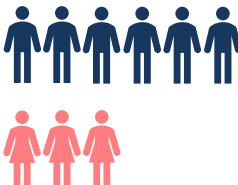
Low Dose – 30 minutes

Cohort 2
3,000mg



✓ *Safe and well tolerated*

Cohort 1
2,500mg



✓ *Safe and well tolerated*

Topical Clinical Programs

Phase I/II Clinical Trial – Treatment of Burn Wound Infections

- **Stage 1 Complete**
- Patients treated with R327 showed **good indications of safety and tolerability**
- **No serious adverse events** reported among patients
- Clinical investigators are preparing a new protocol of next stage
- **Stage 2 clinical trial** expected to be a randomised 'head-to-head' in patients with infected burn wounds, where R327G treatment is compared to existing treatment standard of care

Phase I/II Clinical Trial – Diabetic Foot Infections

- **Ongoing and dosing patients**
- Patients supported by in-home (out-patient) nurses trained in R327 treatment protocols
- Appointment of leading out-patient nursing group sees broadening of DFI patient trial population – increased probability of dosing completion
- Study across South Western Sydney health district – one of the highest prevalence rates of diabetes in NSW
- **Largest DFU study underway in Australia at this time**



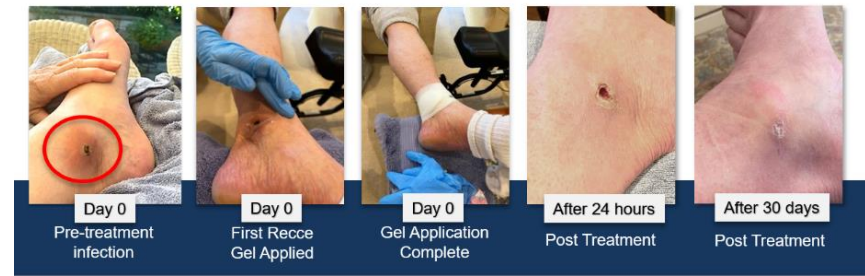
For illustrative purposes only – not final product



TGA

Special Access Scheme

Case Studies



Robust Worldwide Intellectual Property Portfolio

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

Filed	Patent Family 1	Expiry	Patent Family 2	Expiry	Patent Family 3	Expiry	Patent Family 4	Expiry
Australia	✓	2028	✓	2037	✓	2037	✓	2041
USA	✓	2029	✓	2037	✓	2037	Pending	-
Europe	✓	2028	✓	2037	✓	2037	Pending	-
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	Pending	-
China	✓	2028	Pending	2037	✓	2037	Pending	-
HK	Pending	2028	Pending	2037	✓	2037	Pending	-
Israel	-	-	-	-	-	-	Allowed	2041
Canada	-	-	-	-	-	-	Allowed	2041

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

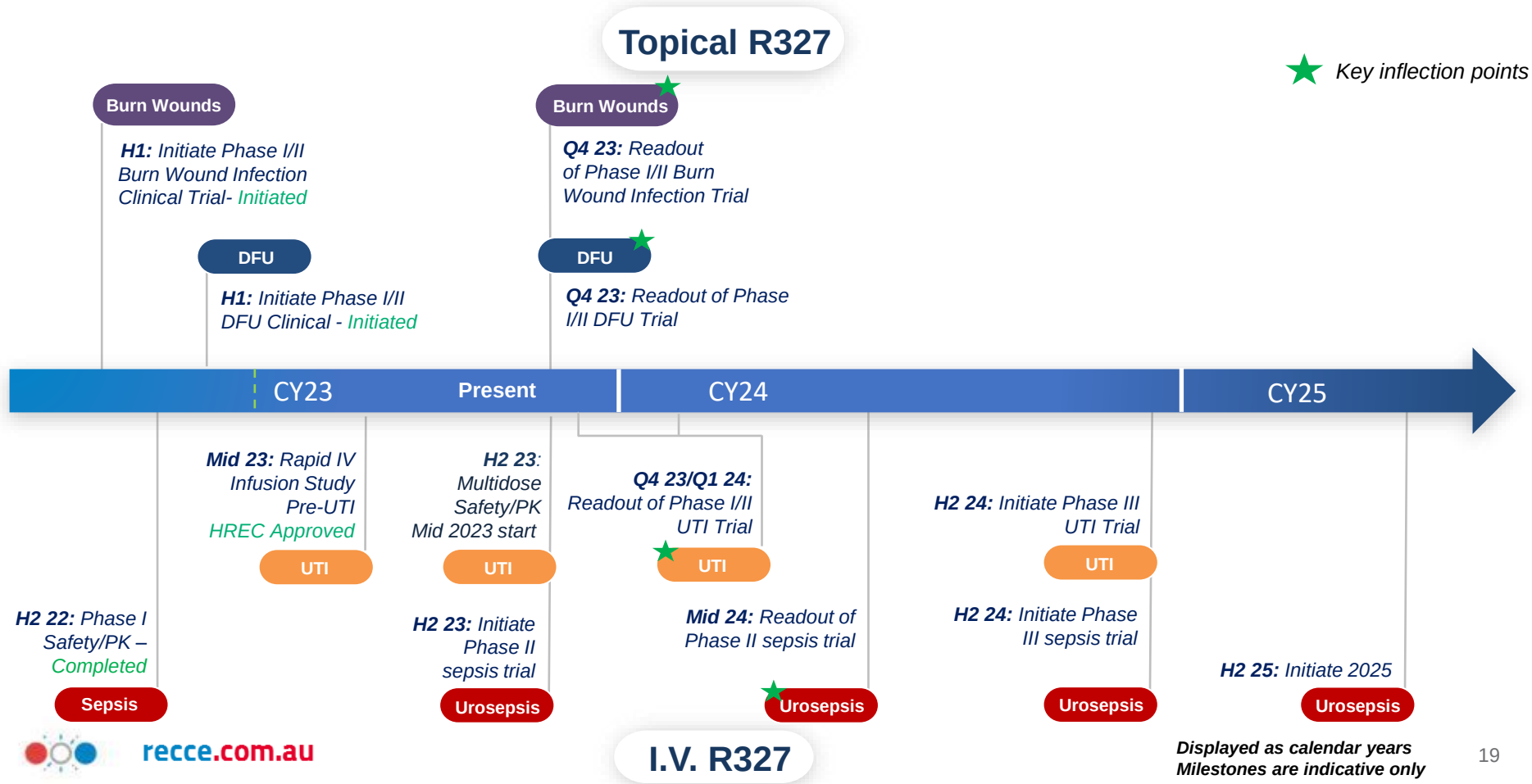
Family 2 relates to the Method of Manufacture, Administration and Application to Treat a Broad Range of Common Human Infections.

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

Family 4 relates to Process for Preparation of Biologically Active Copolymer, other Patent Cooperation Treaty countries pending/allowed)



Multiple Upcoming Clinical Milestones



Thank you

James Graham

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