

CEO Presentation

ASX:RCE | FSE:R9Q

November 2024

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About Recce Pharmaceuticals Ltd

Recce Pharmaceuticals Ltd (ASX: RCE, FSE: R9Q) is developing a new class of Synthetic Anti-Infectives



- Australian clinical-stage biotech company, with a United States presence
- **Qualified Infectious Disease Product designation** – 10 years of 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**
- The **World Health Organization** added RECCE compounds to its list of antibacterial products in clinical development for priority pathogens
- 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.**



Michele Dilizia – Executive Director & Chief Scientific Officer

BSc (Med Sci), Grad Dip Bus (Mktg), 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.



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 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.



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.



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.



recce.com.au

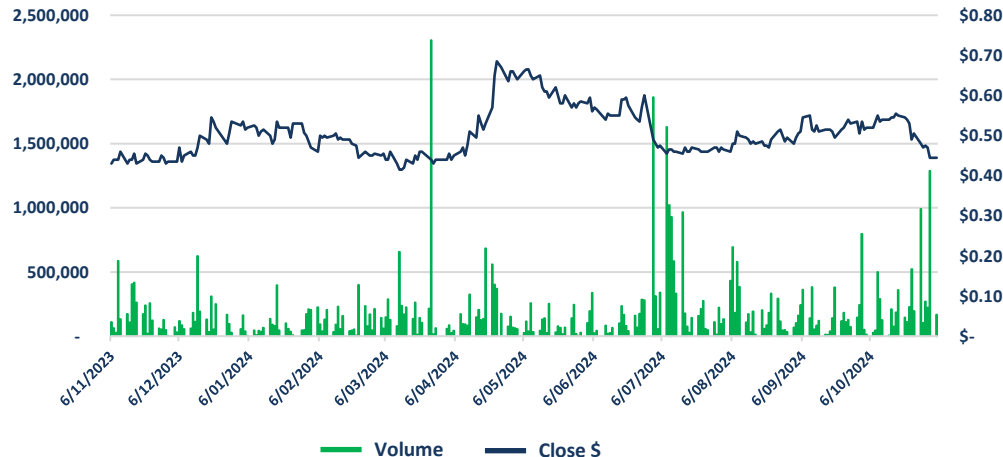
Company Overview

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

Capital Structure – 4th November 2024

ASX & FSE Code	RCE, R9Q
Share Price	AUD \$0.445
3-Month Average Volume	160.08k
Shares on Issue	231.87 million
Unlisted Options (Avg \$1.54)	13.9 million
Market Capitalisation	AUD \$103 million
Cash at Bank	AUD \$6.33 million
Top 20 Shareholders	49.94%

RCE Share Price and Volume Chart – 12 Months



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



Australian Government awarded AUD \$54,947,284 (USD \$37,043,433) Advanced Overseas Finding across RCE infectious disease portfolio**



I.V. and topical treatments advancing for UTI/Urosepsis and ABSSSI including DFI; as well as US Department of Defense Burn Wound Program and Indonesian clinical trials for topical treatments.



Multiple clinical indications and formulations in Phase I and Phase II addressing unmet medical needs: **Sepsis, UTI/Urosepsis, Burn Wounds and Acute Bacterial Skin and Skin Structure Infections (ABSSSI), including Diabetic Foot Infections**

**The Advanced Finding is a binding, underwritten guarantee provided by the Australian Government, which affirms the Company's R&D activities are of national interest and extends the 43.5% R&D rebate from locally, to cover those undertaken by the Company anywhere in the world for a period of three years. This finding does not constitute a grant, or an upfront payment of the amount awarded

At our last AGM – 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



Build Out Presence in the USA

Further expand capabilities in USA supporting FDA strategy



Submit Investigational New Drug (IND) application





Data Review and Completion of Clinical Trials

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

Completed Clinical Trials

Phase I Clinical Trial *Intravenous*

- Complete 80 subject data safety review
- Data provided for safety and tolerability of R327

Phase I/II UTI/Urosepsis Rapid Infusion Clinical Trial *Intravenous*

- Key findings: highest dose of 4,000mg of R327 I.V. over 30 minutes
- Consistent efficacy across participants, clear impact on bacterial growth build-up over time in urine, sustained effectiveness and rapid reduction in bacteria.

Phase I/II Diabetic Foot Infection Clinical Trial *Topical Gel*

- All primary endpoints were met in this trial
- Achievement further solidifies R327's potential across multiple indications

Upcoming Clinical Trial Milestones

Phase II ABSSSI Clinical Trial *Topical Gel*

- 20 of 30 patients dosed - in final stages
- **All patients completing treatment with R327G had a positive primary endpoint** (achieving either complete cure or improvement)

To be completed CY 2024

Phase III Registrational Clinical Trial in Indonesia *Topical Gel*

- Recce has significantly progressed regulatory submissions with the Indonesian Drug and Food Regulatory Authority and Human Ethics Committee
- Phase III trial will be focused on the treatment DFIs - expected to be approved imminently



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**Regulatory approval imminent to commence
Phase III clinical trial**

Phase II ABSSSI Clinical Trial – Dosing in Final Stages

Efficacy Data and Safety Approval Received

- Non-Data Safety Monitoring Board unanimously agree **R327G is safe and well-tolerated in patients** – demonstrating **highly encouraging efficacy results**
- **All patients completing treatment with R327G had a positive primary endpoint - achieving either complete cure or improvement, seen as early as 7 days**
- **20 of 30 total patients dosed**
- **No Serious Adverse Events** noted in patients - recommendation for clinical trial to continue
- **Wide variety of infecting bacteria** (Gram positive and Gram negative) were isolated and **successfully treated** with **Improvement/Cure** of infection in all patients that continued with their treatment.

Patient #	Age (yrs)/Gender	Infection	Clinical Response
Patient 1	88/M	ABSSSI	Cure (Day 7)
Patient 2	53/M	ABSSSI	Cure (Day 7)
Patient 3	49/M	ABSSSI	Cure (Day 7)
Patient 4	63/F	ABSSSI	Cure (Day 7)
Patient 5	46/M	ABSSSI	Cure (Day 14)
Patient 6	63/F	ABSSSI	Cure (Day 14)
Patient 7	67/M	ABSSSI	Improvement (Day 7)
Patient 8	72/M	ABSSSI	Improvement (Day 7)
Patient 9	70/M	ABSSSI	Improvement (Day 7)
Patient 10	59/M	ABSSSI	Improvement (Day 7)
Patient 11	63/M	ABSSSI	Improvement (Day 7)
Patient 12	68/M	ABSSSI	Improvement (Day 14)
Patient 13	81/F	ABSSSI	Withdrawn*
Patient 14	84/F	ABSSSI	Improvement (Day 14)

**While no serious adverse events were noted, one patient was discontinued due to pain at the wound site which was judged to be unlikely related to R327G.*

Large Addressable Market

The global diabetic foot infection (DFI) and sepsis market is worth in excess of \$US9.5 billion

Global Diabetic Foot Infections (DFI) Market

- The DFI treatment market is estimated to be worth ~US\$5.2 billion¹
- Initially targeting Indonesian market valued at ~US\$189m where Diabetes impacts 11% of the population²
- Indonesian approvals provide access to the broader Asia Pacific market worth ~US\$1.0 billion per year³
- The risk of a person with diabetes developing a foot ulcer has been estimated to be as high as 34%⁴
- Approximately 50% of all diabetic foot ulcers develop infection, which can lead to sepsis, gangrene, amputation, and death⁵

US\$5.2B

Global DFI treatment market¹

Global Sepsis Market

- Global sepsis treatment market estimated to be worth ~US\$4.6 billion in 2023 and is projected to grow at a CAGR of 5.5% to reach ~US\$13.7 billion by the end of 2030⁶
- Recce is initially targeting US and Australian markets worth in excess of US\$1.5 billion⁶

US\$4.6B

Global sepsis market⁶

Significant additional market opportunities exist in the broader anti-infectives market, estimated to be worth ~US\$136.9 billion with Recce already exploring opportunities in burn wound infections, skin and soft tissue infections post operation⁷.

Source: (1) Grand View Research, Diabetic Foot Ulcer Treatment Market Size, 2023 (2) Diabetes Atlas, International Diabetic Federation and Prof EM Yunir, Faculty of Medicines, University of Indonesia. (3) Business Market Insights, Asia Pacific Diabetic Foot Ulcer Market, 2021 (4) The Diabetic Foot NCBI (5) Up to Date Evaluation of the diabetic foot (6) ResearchandMarkets, Global Sepsis Therapeutics, 2024 (7) Grand View Research, Anti-Infective Agents Market Size, 2023





Government/Private Enterprise Partnerships

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

Domestic Partnerships & Funding

Awarded AusIndustry Advanced Overseas (R&D) Finding

- Recce awarded AUD \$54,947,284 across infectious disease portfolio for applicable R&D expenditure for its Synthetic Antibiotic and Anti-Viral R&D
- Largest awarded in Australian history and extends the 43.5% R&D rebate from locally, to cover those undertaken by the Company anywhere in the world for a period of three years

Continued Collaboration with Murdoch Children's Research Institute (MCRI)

- Collaboration with MCRI remains a pivotal element of Recce's strategy
- Enables Recce to tap into ground-breaking research and clinical expertise to bolster pipeline

Global Partnerships & Funding

Memorandum of Understanding (MoU) with PT Etana Biotechnologies (Etana)

- Initiative supported by the Australian and Indonesian Governments
- Collaboration accelerates late-stage clinical programs and expands reach into the broader ASEAN market.

US Department of Defense granted R327 Gel (R327G) as a topical treatment for Burn Wound Infections

- Grant funding of USD \$2 million (AUD \$3 million)
- R327G will be evaluated as a gel-impregnated wound dressing to treat burn wounds in active military scenarios





Build out Presence in the USA

Further expand capabilities in USA supporting FDA strategy

Active Engagement in US Focused Conferences and Landmarks

- Opening Keynote Address and Opening R&D Address at the World Anti-microbial Resistance Congress
- Presented at US BIO 2024, the largest and most comprehensive event in the world for biotechnology
- Attended JP Morgan Healthcare Conference
- Featured on the NASDAQ Tower in Times Square, New York City

Collaboration with US Military and BARDA

- Burn wound program grant of USD \$2 million
- Presented to the Biomedical Advanced Research and Development Authority (BARDA)
- Research Abstract and Poster presentation published at the 2024 Military Health System Research Symposium (MHSRS) – US Department of Defence's foremost scientific meeting
- Delivered presentation to the Defence Threat Reduction Agency (DTRA) at the Techwatch Seminar

Scouting US Locations for Manufacturing

- Ensuring Recce has the infrastructure in place to support FDA strategy and future market needs



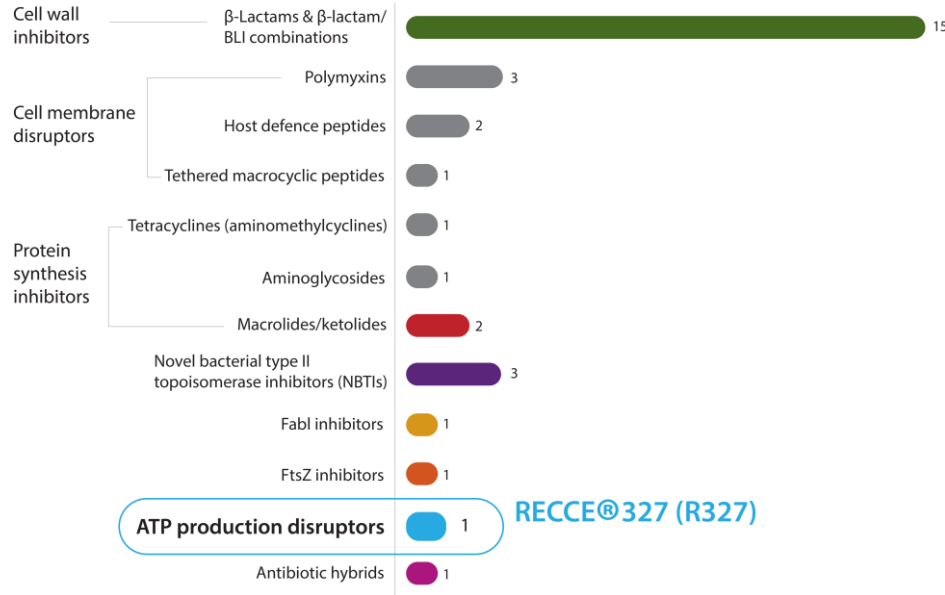
U.S. Army Medical Research and Materiel Command



RECCE® 327 – Global Recognition

R327 added to World Health Organization's List of Antibacterial Products in Clinical Development

Distribution of traditional agents according to their antibiotic class



- Global recognition by the **World Health Organization (WHO)** – inclusion underscores significance of R327 in combating antimicrobial resistance.
- Unique Mechanism of Action – R327 uniquely classified as an adenosine triphosphate (ATP) production disruptor, the **only compound under this category**.
- **R327 recognised as a novel treatment** for a broad range of life-threatening and resistant bacteria.
- The report covers traditional and non-traditional antibacterial agents in development worldwide and evaluates to what extent the present pipeline addresses infections caused by priority pathogens.



Global Regulatory Strategy

Expansion into Indonesia

- Pursuing similar regulatory pathway in Indonesia
- Leveraging MoU with PT Etana to facilitate local regulatory process
- Successfully completing Phase III registrational trial in Indonesia, enabling Recce to replicate regulatory approval for R327G across broader ASEAN region
 - Countries including Malaysia, Philippines, Singapore and Thailand as a treatment for DFIs

Ongoing IND Preparations

- Actively working with leading expert groups to assist in preparing IND application
 - Those included are Linnaeus Bioscience, leading experts in the analyses of mechanism of action in drugs
- Completion of Phase I, Phase I/II Urinary Tract Infection, Phase I/II Diabetic Foot Infection clinical trials have provided safety, tolerability and efficacy data, a core component of IND dossier

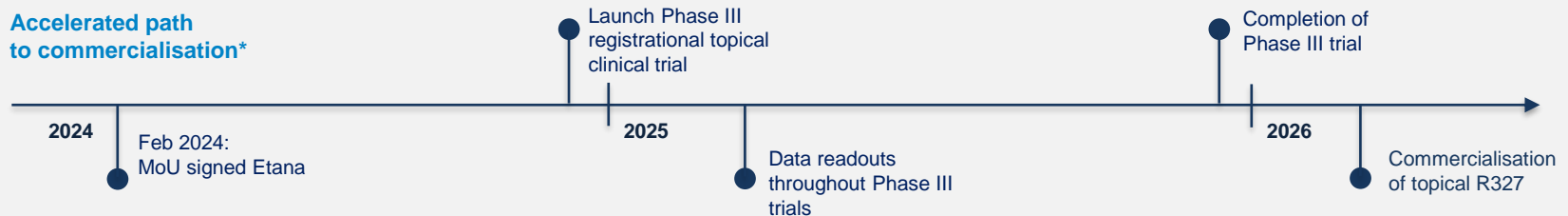
Strategic Opportunity in South-East Asia to Accelerate Clinical Program

- **Memorandum of Understanding (MoU)** with leading Indonesian biomedical company PT Etana Biotechnologies, supporting the Indonesian Government's access to novel infectious disease medicines
- **Significantly progressed regulatory submissions** with the Indonesian Drug and Food Regulatory Authority, Badan POM and an independent Human Ethics Committee.
- Submissions seek **approval to begin a Registrational Phase III clinical trial in Indonesia**
- A successful outcome in this trial would represent a substantial advancement toward market authorisation
- **Opportunity to access 10 ASEAN member states** covering a population of 670 million inhabitants
- **Significant bilateral initiative** supported by Australian and Indonesian Governments



Recce & Badan POM Team's - Recce CEO James Graham (centre left) and Head of Drug and Food Authority Badan POM, Professor Taruna Ikrar (centre)

Accelerated path to commercialisation*



*timeline is indicative only and subject to change

Top 20 Shareholders Movements since last AGM – Increased Support

Position	Holder/Group Name	1-Nov-24	
		Balance	Issued Capital (%) 1 Nov 24
1	Graham Melrose And Olga Melrose	34,828,311	15.02%
2	Hsbc Custody Nominees (Australia) Limited	14,946,039	6.45%
3	M Rogers And A Veliss	10,200,000	4.40%
4	Mr James Graham	9,580,178	4.13%
5	Bnp Paribas Noms Pty Ltd	6,431,223	2.77%
6	Mr John James Liddelow	5,065,249	2.18%
7	Acuity Capital Investment Management Pty Ltd <Acuity Capital Holdings A/C>	4,500,000	1.94%
8	Acewood Investments Pty Ltd <Chivers Super Fund A/C>	3,537,101	1.53%
9	Pejay Pty Limited	3,300,000	1.42%
10	BNP Paribas Nominees Pty Ltd <Clearstream>	2,989,111	1.29%
11	Ms Michele Keryn Dilizia	2,828,485	1.22%
12	LDU Pty Ltd	2,558,429	1.10%
13	J P Morgan Nominees Australia Pty Limited	2,177,007	0.94%
14	Querion Pty Ltd	2,100,000	0.91%
15	Seneschal (WA) Pty Ltd <Winston Scotney Family S A/C>	2,066,666	0.89%
16	Citicorp Nominees Pty Limited	2,043,601	0.88%
17	Haultrans Management Pty Limited <Successful Super Fund A/C>	1,870,000	0.81%
18	Tim Collard	1,838,031	0.79%
19	Mr Nikolai Shirobokov & Mrs Svetlana Shirobokov	1,491,963	0.64%
20	Mr Michael Noel Aarons & Mrs Mami Aarons <The Aarons Superfund A/C>	1,437,498	0.62%
Total		115,788,892	49.94%

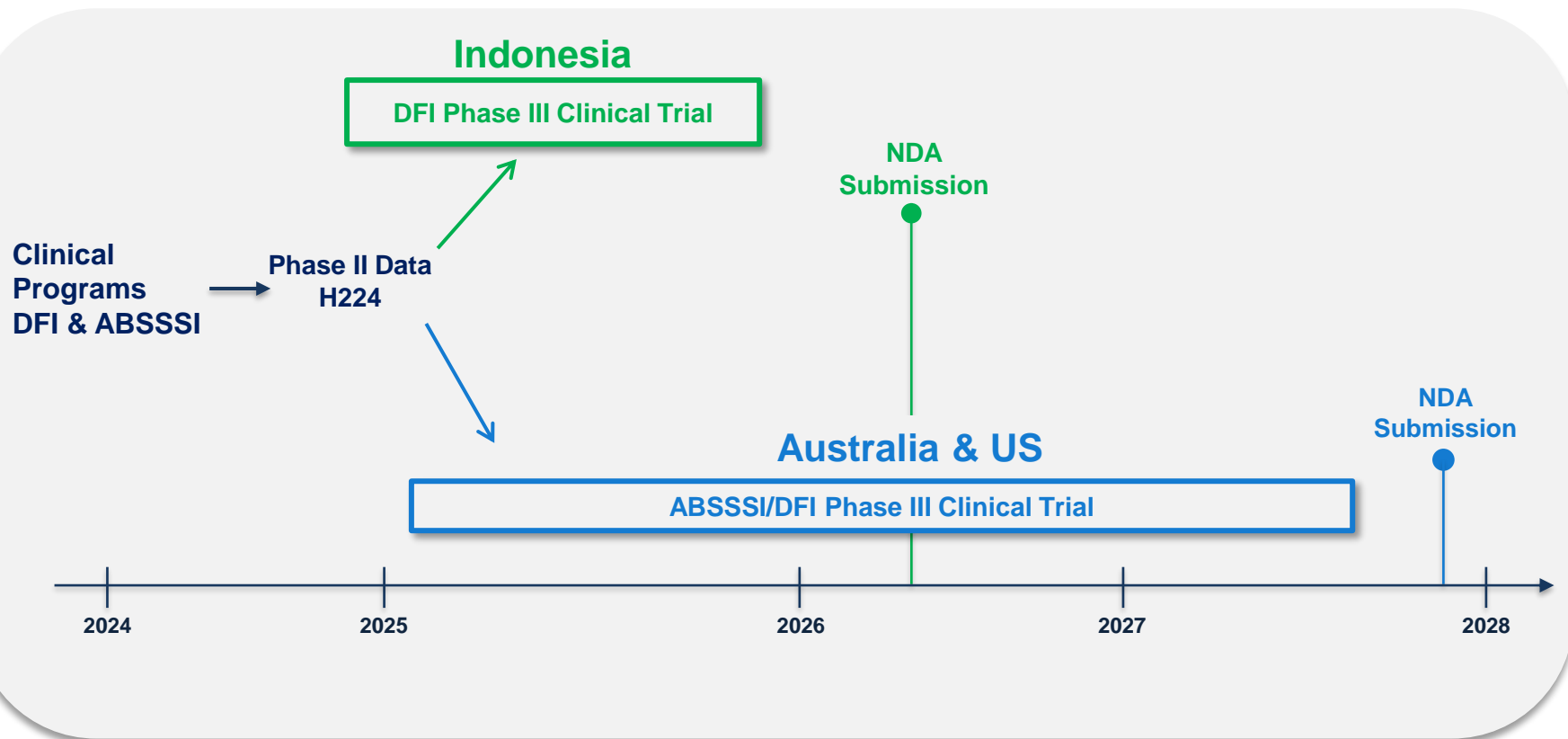
Top 20 holder accumulation
since last AGM

↑ 14,387,712 Shares

Top 20 Shareholding as of 2024

49.94%
of total issued capital

Recce's Commercialisation Pathway



Summary – Significant Value Creating Opportunities



*Phase II Acute Bacterial Skin and Skin Structure Infection **clinical trial to be clinically completed CY24***



***Indonesian Phase III registrational clinical trial data read-out and regulatory submission expected in late 2025,**
potential market approval and commercial launch in H1 2026*



Upon completion of Phase III registrational clinical trial, enables Recce to replicate regulatory approval for R327G across the broader ASEAN region



Australia/NZ Phase III clinical trial of R327G expected to start in H1 2025



Expansion of Recce's Global Regulatory Strategy including US IND and Department of Defense



Thank you

James Graham

Managing Director and Chief Executive Officer

Recce Pharmaceuticals Ltd

ASX:RCE; FSE:R9Q

