Recce Pharmaceuticals (ASX:RCE, FSE:R9Q) Business Update

Highlights:

- **Promising Minimum Inhibitory Concentration (MIC) activity in Phase I/II UTI/Urosepsis Trial with an increase in dosage expected to begin in the next several weeks**
- **Expansion of Phase I/II DFI Clinical Trial with efficacy achieved and now moving towards the initiation of a Phase III registrational trial in Indonesia scheduled to commence Q3 2024**
- **RECCE® 327 tested against over 300 strains of bacterial pathogens and shown to be effective against all during testing with Linnaeus Bioscience**
- **US Department of Defence has recommended RECCE® 327 Gel (R327G) as a topical treatment for Burn Wound Infections for grant funding of USD $2.2 million (approximately AUD 3.34 million)**
- **Submission of Investigational New Drug (IND) Application with the US FDA expected in H2 2024 for US trial initiation in H1 2025**
- **Continued recognition and awareness of Recce with presentations recently presented at Biomedical Advanced Research and Development Authority (BARDA), Opening Keynote Address and Opening R&D Address at the World AMR Congress 2024 and sponsorship received from WA and NSW Government for BIO International Convention 2024**

Sydney Australia, 8 April 2024: Recce Pharmaceuticals Limited (**ASX:RCE, FSE:R9Q**) (**Recce** or the **Company**), a leading developer of a new class of Synthetic Anti-Infectives, is pleased to provide a business update highlighting various ongoing activities and progress made since the Annual General Meeting held on 8 November 2023.

Detailed Update:

Progress of R327 across Multiple Indications

(UTI/Urosepsis, DFI, Topical Wounds, SAS-A)

Phase I/II UTI/Urosepsis Trial – R327 achieving Minimum Inhibitory Concentration (MIC)

The Company is making significant strides in its Phase I/II UTI/Urosepsis faster infusion clinical trial. **Recent clinical urine samples have indicated promising MIC activity, suggesting that fast infusion of R327 leads to concentrations capable of blocking the growth of bacteria in urine** (relevant to UTI/Urosepsis patient treatment) in a safe and tolerable manner. This promising finding has prompted the Company to **increase the dosage of R327 in this Phase I/II trial to its highest level yet, at a rate of 4,000mg infused over 30 minutes, which is expected to begin in the next several weeks**. This escalation reflects the excitement surrounding R327's potential to address critical medical needs in the treatment of UTIs and urosepsis.

Diabetic Foot Infection (DFI) Efficacy Achieved: Expansion of Phase I/II DFI Clinical Trial

Recce is actively pursuing an expansion of its clinical trial sites for its Phase I/II DFI clinical trial, with **notable sites identified and are expected to come online during the present quarter**: one of the largest and most comprehensive regional health services in Australia based out of Victoria, and a world-class private hospital in, Western Australia.

This strategic initiative aims to access a greater patient population, enhancing the diversity and depth of clinical data gathered. By forging collaborations with these esteemed institutions, the Company demonstrates its commitment to advancing medical research and delivering innovative solutions that could potentially transform patient outcomes.

The Company is actively advancing its latest international expansion in Indonesia for a DFI clinical trial, moving steadily towards the initiation of a Phase III registrational trial scheduled to commence Q3 2024.

R327 works and keeps on working with repeated use: tested in over 300 Strains of Bacterial Pathogens – Effective Against All

The Company continues to work with leading experts, dedicated to the discovery and

recce.com.au
ACN 124 849 065

Chief Executive Officer
James Graham
Recce Pharmaceuticals Ltd
james.graham@recce.com.au

Media and Investor Relations

Australia
Andrew Geddes
CityPR
+61 408 677 734
ageddes@citypublicrelations.com.au

USA
Michael Fitzhugh
LifeSci Communications
mfitzhugh@lifescicomms.com

Europe
Guillaume van Renterghem
LifeSci Advisors
gvanrenterghem@lifesciadvisors.com

development of innovative technologies, Linnaeus Bioscience, where they have tested R327 against over 300 strains between the ESKAPEE group of pathogens (198 Gram-negative and 111 Gram-positive bacteria strains). Chief Operations Officer Hannah Tsunemoto Ph.D. led the experiments against these pathogens and commented that: **"*R327 is effective against all strains tested at MICs*".**

Gram-positive representatives

Bacteria	Strains
Enterococcus spp.	33
S. aureus	65
Enterobacter spp.	13
Total	**198**

Gram-negative representatives

Bacteria	Strains
K. pneumoniae	38
A. baumannii	53
P. aeruginosa	63
Salmonella	4
E. coli	40
Total	**111**

More than 95% of the strains tested were clinically isolated from a variety of sources, including but not limited to wounds, blood, urine and sputum (phlegm).

Furthermore, in a **31-day sub-MIC serial exposure study**, R327 was tested against a Multi-Drug Resistant (MDR) strain of *Escherichia coli (E. coli)* and **showed no evidence of induced resistance to R327**.

Submission of Investigational New Drug (IND) Application with the US FDA expected in H2 2024 for U.S. trial initiation in H1 2025

The Company has been making significant strides in preparing for an investigational new drug (IND) application with the U.S. Food and Drug Administration (FDA). One of the pivotal initiatives contributing to this progress is the successful ongoing Phase I/II UTI/Urosepsis rapid infusion clinical trial. The completion of the Phase I clinical trial marked a crucial milestone for the Company, providing valuable data on the safety and tolerability of R327 required as part of the IND Application dossier.

As the Company continues to generate promising interim data from its Phase I/II UTI/Urosepsis clinical trial on both safety and efficacy, R327 is showcasing its capability to be administered over multiple fast infusion times, highlighting the potential for a ground-breaking treatment on the first patient presentation in any medical setting. These achievements collectively position Recce on track with its upcoming IND application, underscoring the company's dedication to bringing novel therapies to market swiftly and responsibly.

recce.com.au
ACN 124 849 065

Media and Investor Relations

Chief Executive Officer
James Graham
Recce Pharmaceuticals Ltd
james.graham@recce.com.au

Australia
Andrew Geddes
CityPR
+61 408 677 734
ageddes@citypublicrelations.com.au

USA
Michael Fitzhugh
LifeSci Communications
mfitzhugh@lifescicomms.com

Europe
Guillaume van Renterghem
LifeSci Advisors
gvanrenterghem@lifesciadvisors.com

The Company expects to open a second IND application for all topical work conducted to date soon after the I.V. IND application.

Government/Private Enterprise Partnerships and Presence in the USA

Recce has been actively pursuing various grant applications and submissions, particularly in Government antimicrobial resistance (AMR) initiatives and military and health security.

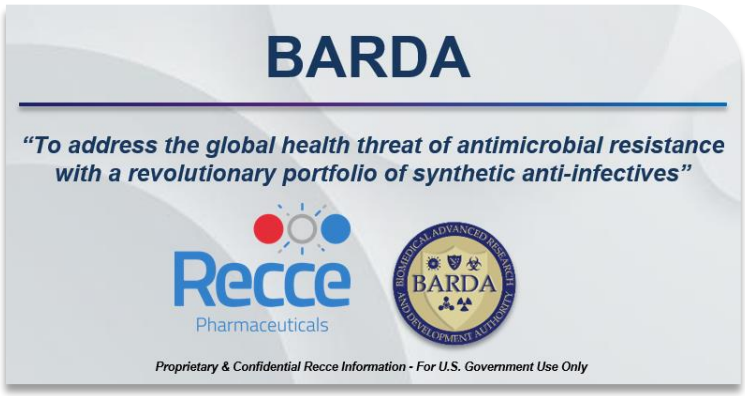
US Department of Defence: Recommended for USD $2.2M (AUD $3.34M) Grant Funding

As a result of the Company's efforts in the military sector, the US Department of Defence has **Recommended R327 Gel (R327G) as a topical treatment for Burn Wound Infections for grant funding of USD $2.2 million (AUD 3.34 million)**.

Once awarded, the funding will enable the Company to accelerate the development and evaluation of R327G and evaluate it as a gel-based treatment to rapidly resolve burn wound infections and minimise the onset of bacteraemia complications, such as sepsis. This milestone emphasises the Company's significant contributions to military health research. Recce expects funding to be received in H1 2024.

Biomedical Advanced Research and Development Authority (BARDA) Presentation

Recce delivered a company presentation at the request of the U.S. **Biomedical Advanced Research and Development Authority (BARDA)**, further strengthening its relationship and collaboration with US governmental organisations.



BARDA has specific Areas of Interest that it focuses on for funding, where R327 fits into two categories: **Antimicrobials** (3.1 Multi-drug resistant Bacteria and Biothreat Pathogens) and **Burn and Blast Medical Countermeasures** (6.4 Non-Autologous Topical Products for Acute bacterial skin and skin structure infections). The presentation was well received and attended by members of the US government from respective military fields.

recce.com.au
ACN 124 849 065

Chief Executive Officer
James Graham
Recce Pharmaceuticals Ltd
james.graham@recce.com.au

Media and Investor Relations

Australia
Andrew Geddes
CityPR
+61 408 677 734
ageddes@citypublicrelations.com.au

USA
Michael Fitzhugh
LifeSci Communications
mfitzhugh@lifescicomms.com

Europe
Guillaume van Renterghem
LifeSci Advisors
gvanrenterghem@lifesciadvisors.com

WA and NSW Government Sponsor Recce for BIO International Convention 2024

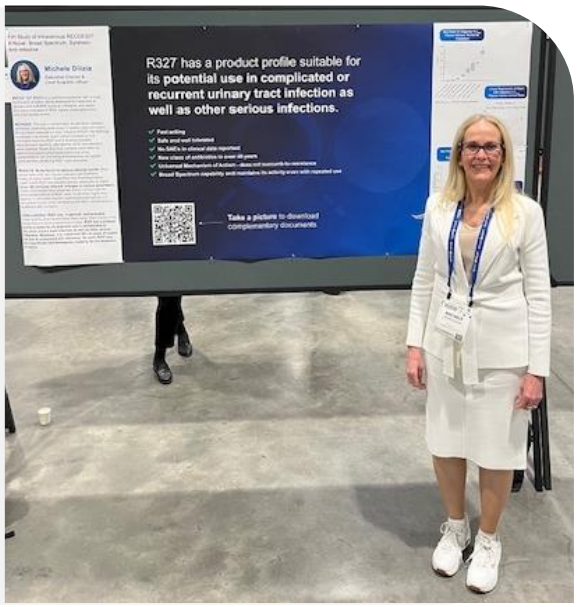
The BIO International Convention is the largest and most comprehensive event for biotechnology, representing the full ecosystem of biotech with over 20,000 industry leaders from across the globe. As part of the Company's national Government initiatives, Recce has been successfully selected to be part of the Western Australia and New South Wales delegation at BIO 2024, highlighting its regional support and recognition within the biopharmaceutical community. These initiatives collectively demonstrate Recce's dedication to advancing innovative solutions in healthcare through strategic collaborations and impactful research endeavours.

World AMR Congress 2024: Opening Keynote Address and the Opening R&D Address

The Company has received another prestigious invitation to present the opening R&D Address at the World AMR Congress. In recognition of its global initiatives, the Company has also been privileged with the opportunity to deliver the opening keynote address for the entire congress. Dr. John Prendergast will deliver the opening R&D address, while Dr. Alan W. Dunton, Recce's Chief Medical Advisor and Non-Executive Director, will open the Congress with the Opening Keynote.

Poster Presentation - American Society for Clinical Pharmacology and Therapeutics

Michele Dilizia, Chief Scientific Officer and Co-inventor of RECCE® technology, presented a poster based on the results of Recce's Phase I clinical trial at the American Society for Clinical Pharmacology and Therapeutics (ASCPT) Annual Meeting, showcasing the company's scientific advancements. The annual meeting serves as a multi-disciplinary catalyst for emerging science, focused on the integrity and diversity of clinical pharmacology and translational medicine.



recce.com.au
ACN 124 849 065

Media and Investor Relations

Chief Executive Officer
James Graham
Recce Pharmaceuticals Ltd
james.graham@recce.com.au

Australia
Andrew Geddes
CityPR
+61 408 677 734
ageddes@citypublicrelations.com.au

USA
Michael Fitzhugh
LifeSci Communications
mfitzhugh@lifescicomms.com

Europe
Guillaume van Renterghem
LifeSci Advisors
gvanrenterghem@lifesciadvisors.com

Military Health System Research Symposium (MHSRS) Abstract Submission

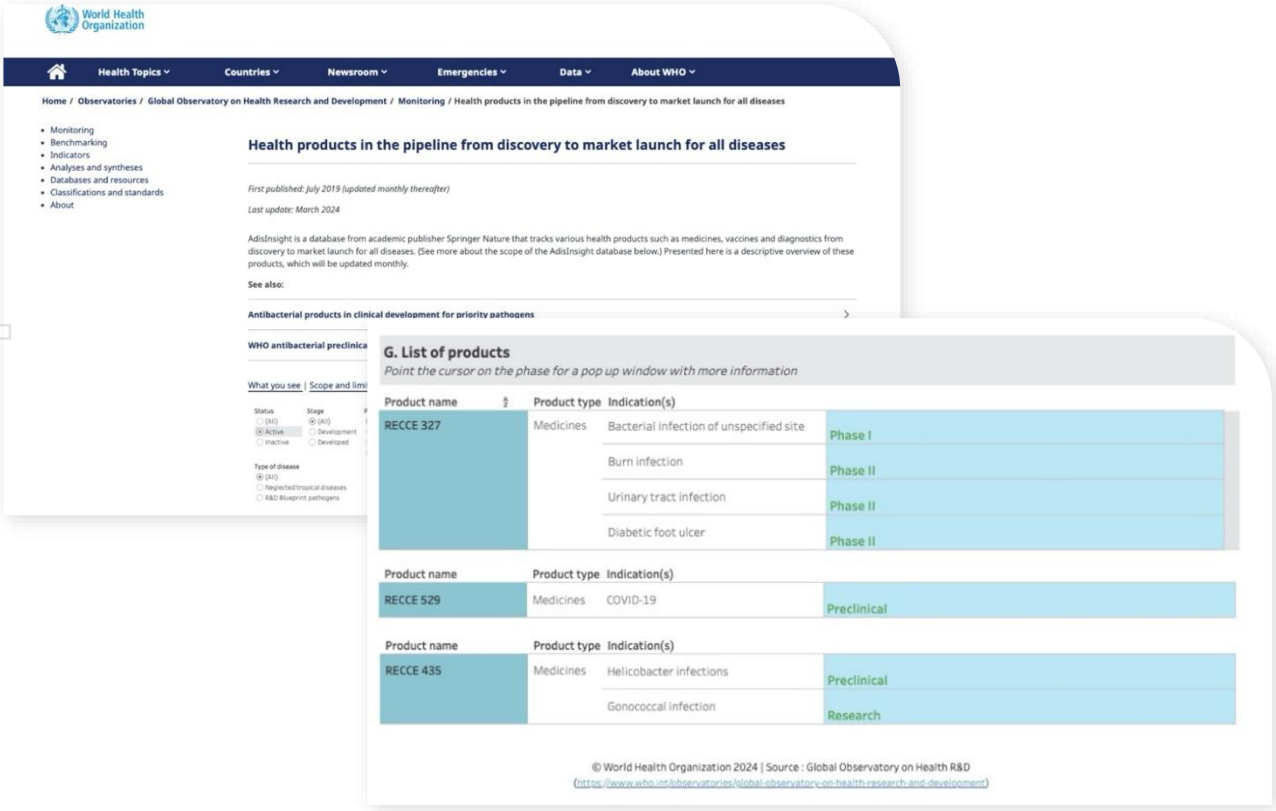
As was delivered in 2023, the Company has again submitted an abstract for MHSRS 2024, building on its successful participation in 2023 and anticipating further success this year. The MHSRS is the US Department of Defence's foremost scientific meeting, presenting new scientific knowledge particular to military specific R&D.

Additional Operational Activities

World Health Organization Recognition

R327, along with R435 and R529, gained recognition from the World Health Organization (WHO) by being added to their list of antibacterial products in clinical development for priority pathogens.

This acknowledgment highlights the potential of RECCE® compounds to address critical global health challenges posed by antibiotic-resistant bacteria. Being included in the WHO's evaluation signifies the importance of Recce's research and development efforts in combatting infectious diseases. The WHO annually assesses antibacterial products, which involves an evaluation comparing these products in development with the WHO's list of antibiotic-resistant bacterial priority pathogens.



recce.com.au
ACN 124 849 065

Chief Executive Officer
James Graham
Recce Pharmaceuticals Ltd
james.graham@recce.com.au

Media and Investor Relations

Australia
Andrew Geddes
CityPR
+61 408 677 734
ageddes@citypublicrelations.com.au

USA
Michael Fitzhugh
LifeSci Communications
mfitzhugh@lifescicomms.com

Europe
Guillaume van Renterghem
LifeSci Advisors
gvanrenterghem@lifesciadvisors.com

R&D Advance Initiatives – Endpoints Capital

The Company continues to strengthen its strategic partnership with Endpoints Capital after securing a significant $11.2 million in non-dilutive funding, reinforcing its R&D initiatives for FY23/24 and into the future. This financial support, **augmented by the Advanced Overseas Finding from the Australian Government**, expands Recce's R&D horizons globally.

For more insights into this partnership, Recce and Endpoints have released an on-camera podcast interview that discusses the influence of their collaboration on Recce's growth and the biotech industry.

This announcement has been approved for release by Recce Pharmaceuticals Board.

recce.com.au
ACN 124 849 065

Chief Executive Officer
James Graham
Recce Pharmaceuticals Ltd
james.graham@recce.com.au

Media and Investor Relations

Australia
Andrew Geddes
CityPR
+61 408 677 734
ageddes@citypublicrelations.com.au

USA
Michael Fitzhugh
LifeSci Communications
mfitzhugh@lifescicomms.com

Europe
Guillaume van Renterghem
LifeSci Advisors
gvanrenterghem@lifesciadvisors.com

About Recce Pharmaceuticals Ltd

Recce Pharmaceuticals Ltd (ASX: **RCE**, FSE: **R9Q**) is developing a New Class 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 includes three patented, broad-spectrum, synthetic polymer anti-infectives: RECCE® 327 as an intravenous and topical therapy that is being developed for the treatment of serious and potentially life-threatening infections due to Gram-positive and Gram-negative bacteria including their superbug forms; RECCE® 435 as an orally administered therapy for bacterial infections; and RECCE® 529 for viral infections. Through their multi-layered mechanisms of action, Recce's anti-infectives have the potential to overcome the hypercellular mutation of bacteria and viruses – the challenge of all existing antibiotics to date.

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 world's only synthetic polymer and sepsis drug candidate in development. RECCE® 327 is not yet market approved for use in humans with further clinical testing required to fully evaluate safety and efficacy.

Recce wholly owns its automated manufacturing, which is supporting present clinical trials. Recce's anti-infective pipeline seeks to exploit the unique capabilities of its technologies targeting synergistic, unmet medical needs.

recce.com.au
ACN 124 849 065

Chief Executive Officer
James Graham
Recce Pharmaceuticals Ltd
james.graham@recce.com.au

Media and Investor Relations

Australia
Andrew Geddes
CityPR
+61 408 677 734
ageddes@citypublicrelations.com.au

USA
Michael Fitzhugh
LifeSci Communications
mfitzhugh@lifescicomms.com

Europe
Guillaume van Renterghem
LifeSci Advisors
gvanrenterghem@lifesciadvisors.com