ASX Announcement

Recce Pharmaceuticals
recce.com.au
ACN 124 849 065

Quarterly Cash Flow Statement & Operational Highlights

Highlights:

- **Positive data from Phase I/II UTI/Urosepsis Rapid Infusion Clinical Trial of RECCE® 327 (R327)**
- **Ethics approval to centralise and broaden R327 Gel Clinical Trials across Topical Bacterial Skin Infections including Acute Bacterial Skin and Skin Structure Infections (ABSSSI)**
- **Positive efficacy data from Murdoch Children's Research Institute in pre-clinical study for Lung Infections**
- **R327 added to The World Health Organization's List of Antibacterial Products in Clinical Development**
- **Recce completes 5,000 R327 doses a week under Good Manufacturing Practice (GMP)**
- **Israel & China Patent Granted for RECCE® Anti-Infectives**
- **A$8.0 million institutional placement complete and ~A$2.0 million Share Purchase Plan opens to shareholders to raise up to a total of ~A$10.0 million**
- **Pro-forma cash position of A$16.0 million**

SYDNEY Australia, 26 July 2024: Recce Pharmaceuticals Ltd (**ASX:RCE**, **FSE:R9Q**) (**Recce** or the **Company**), the Company developing a New Class of Synthetic Anti-infectives, today released its June 2024 quarter results and operational highlights.

Financial Update

The Company ended the quarter with a cash balance of $4.4 million. Net cash outflows from operating activities were ($2.1 million), with Research and Development of ($4.0 million) being the largest item of expenditure supporting ongoing human clinical trials, and the advancement of late-stage pre-clinical studies. Payments to related parties (Executive & Director fees) was ($0.78 million).

Additional funding was secured subsequent to the end of the quarter by way of a ~A$3.0 million grant from the US Department of Defense, a successfully completed A$8.0 million institutional placement (before costs) and currently open A$2.0 million SPP. This ensures the Company is well funded with a pro-forma cash balance of A$16.0 million.

Institutional placement and Share Purchase Plan to raise ~A$10.0 million

Post-quarter, the Company completed an institutional placement of A$8.0m and opened a Share Purchase Plan (**SPP**) to shareholders for an additional ~A$2.0m, with total funds expected of ~A$10.0 million. The Company successfully raised $8.0 million (before costs) in a placement of new fully paid ordinary shares in the Company to institutional and sophisticated investors (**Placement**). A SPP with a target raise of A$2.0 million to shareholders is underway and will close at 5:00pm Wednesday, 31 July 2024.

Research and Development (R&D) Tax Incentive rebate – additional cash refund of A$2.6m from the Australian Tax Office

The Company announced a further cash refund of AUD $2.62m Research and Development (R&D) Tax Incentive rebate from the Australian Tax Office for the financial year ending 30 June 2023. The AUD $2.62m reflects R&D activities specifically undertaken overseas and are provided to the Company in cash, without caveat. The Australian portion (AUD $2.3 million) was received late in 2023 and brings FY23 R&D rebates to completion.

Operational Highlights

Positive Data from Phase I/II UTI/Urosepsis Rapid Infusion Clinical Trial of R327

The Company announced positive data from the Phase I/II Rapid Infusion clinical trial for UTI/Urosepsis, demonstrating that R327 administered intravenously is safe and efficacious against *Escherichia coli* (*E. coli*). The Phase I/II study included 25 participants who received R327 at doses up to 4,000mg as intravenous infusions over various infusion times (15-mins, 20-mins, 30-mins and 45-mins). The highest dose cohort included six participants, all receiving 4,000mg of R327 over a 20-minute infusion period.

Key Findings from Clinical Trial at the Highest Dose of 4,000 mg of R327:

Consistent efficacy across participants: Most participants demonstrated significant R327 activity in their urine samples, particularly in the first hour post-dose. The concentrations achieved

were sufficient to impact bacterial growth, indicating that R327 accumulates effectively in the urinary tract.

Clear impact on bacterial growth build-up over time in urine: In the most recent 4,000mg cohort, the study evaluated urine samples from six participants, with 10 urine samples per participant taken over a 6-hour period. Each urine sample was then tested *ex vivo* for its ability to impact the growth of *E. coli*, measured by an increase or decrease in luminescence. All six participants demonstrated a reduction in the rate of bacterial growth over time, with peak efficacy most often achieved 2 to 4 hours post-infusion.

Sustained effectiveness: The trial data revealed that R327's effect on bacterial growth was sustained over time, with significant activity noted not only within the initial 0 to 45-minute window but also extending up to 2 to 4 hours post-dosing. This extended period of activity suggests that R327 maintains its efficacy for prolonged durations, potentially enhancing its therapeutic value in clinical settings.

Rapid reduction in bacteria: In a previous study assessing the time it takes R327 to kill *E. coli* bacteria, R327 was shown to work faster than any other antibiotic to date, measured in minutes – not hours. This is an important feature of R327 and suggests the compound may be able to provide rapid relief to patients.

Ethics approval to centralise and broaden R327 Gel Clinical Trials across Topical Bacterial Skin Infections including Acute Bacterial Skin and Skin Structure Infections

The Company received Human Research Ethics Committee (HREC) approval to commence a Phase II clinical trial assessing R327 as a topical, broad-spectrum gel applied to Acute Bacterial Skin and Skin Structure Infections (ABSSSI).

The Phase II clinical trial is an Open-label, Efficacy Study and Exploratory Evaluation of the Systemic Bioavailability of Single and/or Multiple Doses of R327 Topical Gel Applied to ABSSSI. The study aims to provide critical data on the gel's effectiveness in treating a broad range of ABSSSI indications.

The Company is working with Barwon Health, one of the largest and most comprehensive regional health services in Australia, working alongside existing leading healthcare providers to broaden the

scope of its topical administration. This will enable the trial to access a diverse patient population and provide valuable insights into the gel's performance across various ABSSSI conditions.

Business Update

The Company provided a business update highlighting various ongoing activities and progress made since the Annual General Meeting held on 8 November 2023.

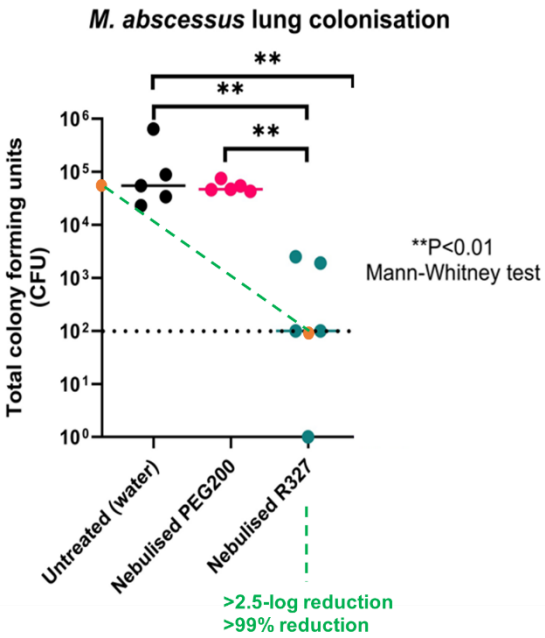
Key Highlights:

- Diabetic Foot Infection (DFI) Efficacy Achieved, Expansion of Phase I/II DFI Clinical Trial
- Phase I/II UTI/Urosepsis Trial – R327 achieving Minimum Inhibitory Concentration (MIC)
- R327 tested against over 300 strains of bacterial pathogens and shown to be effective against all during testing with Linnaeus Bioscience
- Submission of Investigational New Drug (IND) Application with the US FDA expected in H2 2024 for U.S. trial initiation in H1 2025
- US Department of Defense: Recommended for USD $2.2M (A$3.34M) Grant Funding
- World Health Organization (WHO) recognition with R327, R435 and R529 being added to their list of antibacterial products in clinical development for priority pathogens
- Strategic partnership with Endpoints Capital after securing a significant $11.2 million in non-dilutive funding, reinforcing R&D initiatives for FY23/24 and into the future
- 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

Positive Efficacy Data from Murdoch Children's Research Institute in pre-clinical Study for Lung Infections

The Company reported promising results from its latest efficacy study of nebulised R327 for treating lung infections in a mouse model. The study was conducted at Recce's Anti-infective Research (AIR) unit within Murdoch Children's Research Institute.

The study demonstrated a substantial reduction in *Mycobacterium abscessus* (*M. abscessus*) colonisation in both lungs of mice treated with nebulised R327. Notably, nebulised R327 significantly decreased *M. abscessus* bacterial colonisation, and the mice maintained a stable body weight throughout the study period, indicating the treatment's safety and tolerability. This study represents an important step towards exploring new methods of administration across a broad range of therapeutic indications, which pose an increasing threat in healthcare settings globally.



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

The Company announced its primary anti-infective candidate, R327, has been added to the World Health Organization's (WHO) report of Antibacterial Agents in Clinical Development and Preclinical Development and to what extent the present pipeline addresses infections caused by priority pathogens.

R327 was defined by the WHO as 'New Chemical Entity', a novel compound and an ATP production disruptor - **the only compound under this category**. ATP is the source of energy for use and storage at the cellular level. Disruption of ATP production in bacterial cells when targeted as the main mechanism of action, not secondary to other cell perturbation mechanisms, supports the known capability against both Gram-positive and Gram-negative pathogens.

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Annex 13. ATP production disruptors

Product name (INN or company code):
RECCE 327 (R327)

Pharmacology: chemical class and MoA: RECCE 327 (R327) is a fully synthetic (acrolein) polymer designed to disrupt bacterial energy (ATP) production, cell growth and division.

Spectrum of activity and potential resistance: In vitro (poster) data suggest broad-spectrum antibacterial activity against MDR strains of Gram-positive and Gram-negative bacteria, including *Enterococcus faecium*, *S. aureus*, *K. pneumoniae*, *A. baumannii*, *P. aeruginosa* and *Enterobacter* spp. (Recce Pharmaceuticals, unpublished data, 2021) (*1*). In vivo (poster) activity in these "ESKAPE" pathogens has also been described in mouse model studies for kidney and UTI bacterial infection (Recce Pharmaceuticals, unpublished data, 2021) (*1*).

Sought therapeutic indication: RECCE 327 is being studied as a broad-spectrum intervention in infected burn wound care and diabetic foot infection, and in cUTI/urosepsis caused by ESBL-producing Enterobacteriaceae.

Route of administration and proposed posology: Intravenous and topical gel/spray.

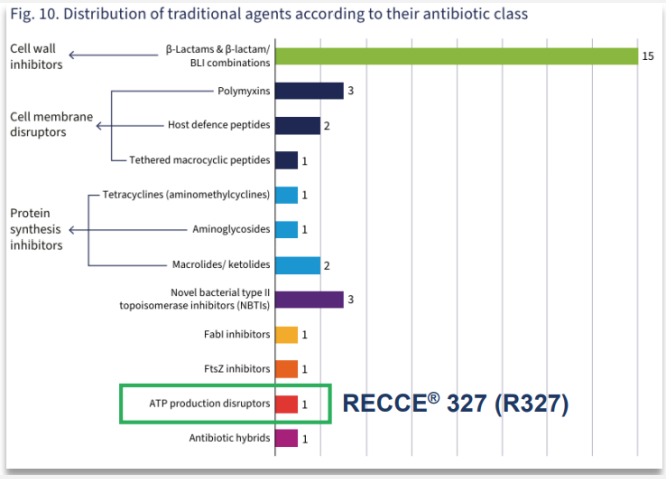
Phase of clinical development: Recent completion of a Phase 1 single iv ascending dose safety and PK study with no publications as yet. Commencement of a Phase 1b/2a proof-of-concept trial for topical application of RECCE 327 for mild diabetic foot infections is planned (*2*).

Clinical trial(s): Four trials are listed in the Australian New Zealand Clinical Trials Registry:

- ACTRN12621001313820: a Phase 1 ascending-dose, randomized, placebo-controlled, parallel, double-blind, single-dose, first-in-human study to evaluate the safety and PK of RECCE 327 in 80 healthy male subjects 18–55 years of age (June 2021 to December 2022, completed);
- ACTRN12623000448640: a Phase 1 open-label, adaptive design evaluation, crossover study of the safety and PK/PD of various RECCE 327 intravenous dose and infusion rates;
- ACTRN12623000056695: a Phase 1/2 proof-of-concept study of RECCE 327 topical anti-infective therapy for mild skin and soft tissue diabetes foot infections; and
- ACTRN12621000412831: a Phase 1 proof-of-concept study of RECCE 327 topical antibiotic therapy for infected burn wounds in adults.

Preclinical PK and safety: In vivo poster data describe no adverse clinical signs in rats treated with RECCE 327, and it achieved broad distribution with particular concentration in urine (Recce Pharmaceuticals, unpublished data, 2021). In tests comparing 50 mg/kg and 500 mg/kg of R327 to vehicle control, the antibacterial effect was dose-dependent ($P < 0.050$) (Recce Pharmaceuticals, unpublished data, 2021) (*1*).

Fig. 10. Distribution of traditional agents according to their antibiotic class



Recce Completes 5,000 R327 Doses a Week under Good Manufacturing Practice

The Company announced successful batch completion under Good Manufacturing Practices (GMP) for R327 with the patented manufacturing process now producing 5,000 GMP doses of R327 per week.

Due to the increased demand for R327 required for clinical studies, producing 5,000 doses of R327 per week is a significant achievement that provides surplus sample material for multiple present Phase I, Phase II and an anticipated Registrational Phase III Diabetic Foot Ulcer Infection study ahead.

Israel Patent Granted for RECCE® Anti-Infectives

The company announced the State of Israel Patent Office has formally Granted Recce's new Patent Family 4 for RECCE's anti-infectives: Patent Number 295116, "*Process for Preparation of Biologically Active Copolymer Comprising an Acrolein Derivative and a Polyalkylene Glycol Oligomer*" in Israel, expiry 2041.

This is the first of Recce's wholly owned patents Granted in Israel, with further Patent Cooperation Treaty Country (PCT) submissions in respective stages of review/allowed.

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China Patent Granted for RECCE® Anti-Infectives

The Company announced the China National Intellectual Property Administration has formally Granted a new Patent Family 2 for Recce's anti-infectives "Copolymer and Method for Treatment of Bacterial Infection" in China, expiry 2035.

This is the final of Recce's wholly-owned patents Granted for Family 2, with the Company now patent-protected in all major pharmaceutical markets globally.

Military Health System Research Symposium Abstract & Poster Presentation

The Company has received confirmation a research Abstract and Poster presentation will be published at the 2024 Military Health System Research Symposium (MHSRS). The MHSRS is the United States (US) Department of Defense's foremost scientific meeting that draws approximately 4,000 attendees with focus on the unique medical needs of the Warfighter. The symposium will be held in Kissimmee, Florida 26-29 August 2024.

Session

Non-traditional Treatments and Delivery strategies for Wound infections and Sepsis

Title

RECCE® 327 Demonstrates Bactericidal Activity Against Multi-Drug Resistant Pathogens and Clinical Efficacy in Polymicrobial Wound Infections

Looking Ahead

The Company is well placed to execute on further clinical advancements with a pro-forma cash position of $16.0 million, inclusive of the $3.0 million US Department of Defense grant, recently completed $8.0 million institutional placement and recently announced $2.0 million SPP.

Recce continues to advance its new class of anti-infectives with intravenous and topical treatments for UTI/Urosepsis and ABSSSI including Diabetic Foot Infections (DFI); as well as US Department of Defense Burn Wound Program and Indonesian clinical trials for topical treatments, which present significant opportunities ahead.

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

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Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity	
Recce Pharmaceuticals Ltd	
ABN	**Quarter ended ("current quarter")**
73 124 849 065	June 2024

Consolidated statement of cash flows		**Current quarter**	**Year to date (12 months)**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for	-	-
	(a) research and development	(4,005,387)	(14,030,534)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(448,811)	(1,581,399)
	(d) leased assets	-	-
	(e) staff costs	(232,305)	(1,268,387)
	(f) administration and corporate costs	(165,843)	(1,648,431)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	95,001	172,690
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	2,624,860	5,003,106
1.8	Other	32,154	42,994
1.9	**Net cash from / (used in) operating activities**	**(2,100,329)**	**(13,309,963)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(33,197)	(141,895)
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter	Year to date (12 months)
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	(46,986)	(162,963)
2.6	**Net cash from / (used in) investing activities**	**(80,184)**	**(304,858)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	11,022,445
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	123,728
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(1,987)	(563,343)
3.5	Proceeds from borrowings	-	10,089,358
3.6	Repayment of borrowings	(1,936,612)	(4,217,762)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	14,000	14,000
3.10	**Net cash from / (used in) financing activities**	**(1,924,599)**	**16,468,427**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	8,520,296	1,561,578
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,100,329)	(13,309,963)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(80,184)	(304,858)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(1,924,599)	16,468,427

Consolidated statement of cash flows		Current quarter	Year to date (12 months)
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**4,415,184**	**4,415,184**

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter	Previous quarter
5.1	Bank balances	4,415,184	8,520,296
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other – Trust Account	-	-
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**4,415,184**	**8,520,296**

6.	Payments to related parties of the entity and their associates	Current quarter
6.1	Aggregate amount of payments to related parties and their associates included in item 1	779,509
6.2	Aggregate amount of payments to related parties and their associates included in item 2	Nil

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.

7.	**Financing facilities** *Note: the term "facility' includes all forms of financing arrangements available to the entity.* *Add notes as necessary for an understanding of the sources of finance available to the entity.*	**Total facility amount at quarter end**	**Amount drawn at quarter end**
7.1	Loan facilities	Nil	Nil
7.2	Credit standby arrangements	Nil	Nil
7.3	Other (please specify)	Nil	Nil
7.4	**Total financing facilities**	Nil	Nil

7.5	**Unused financing facilities available at quarter end**	Nil

7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.

8.	**Estimated cash available for future operating activities**	
8.1	Net cash from / (used in) operating activities (item 1.9)	(2,100,329)
8.2	Cash and cash equivalents at quarter end (item 4.6)	4,415,184
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	4,415,184
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	2.10

Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.

8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:

8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer:

8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer:

8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer:

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

Compliance statement

1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.

2 This statement gives a true and fair view of the matters disclosed.

Date: 26 July 2024

Authorised by: The Board
(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.

2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.

3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.

4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [*name of board committee – eg Audit and Risk Committee*]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".

5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.