#### **ASX Announcement**



# **Quarterly Cash Flow Statement & Operational Highlights**

#### **Highlights:**

- Safety Committee Approves Faster Infusion Rate of 15 Minutes in Phase I/II
   Urinary Tract Infection (UTI)/Urosepsis Rapid Infusion Clinical Trial
- First Subjects of Recruited Cohort Dosed Phase I/II UTI/Urosepsis Rapid Infusion
   Clinical Trial
- Positive Efficacy against Escherichia coli in UTI Animal Study from Murdoch Children's Research Institute via intravenous infusion and new direct-to-bladder delivery
- Positive Efficacy against *Neisseria gonorrhoeae* Animal study from Murdoch Children's Research Institute 4-log (99.99%) and 3.5-log (>99.9%) reduction
- Recce Awarded A\$54.9m AusIndustry Advanced Overseas (R&D) Finding for Anti-Infective (A\$43.7m) and Anti-Viral (A\$11.2m) programs
- Canadian Patent Granted for RECCE® Anti-Infectives
- Brazilian Trade Mark Accepted for RECCE® Anti-Infectives
- 2023 Annual General Meeting delivered
- Recce Presents at Ord Minnett Healthcare Forum

**SYDNEY Australia, 30 January 2024:** Recce Pharmaceuticals Ltd (**ASX:RCE**, **FSE:R9Q**) (the **Company**), the company developing a New Class of Synthetic Anti-infectives, today released its December 2023 quarter results and operational highlights.

## **Financial Update**

During the quarter, the Company received an R&D rebate from the Australian Government on its Australian portion of R&D expenditure totalling A\$2.3 million. This receipt was used to repay advances from Radium Capital with the Company ending the quarter with a cash balance of \$4 million. Net cash outflows from operating activities were A\$2.3 million, with Research and Development (A\$3.6 million) being the largest item of expenditure supporting ongoing human clinical trials and the advancement of ongoing pre-clinical studies. Payments to related parties (Executive, Director and consulting fees) were A\$1.2 million. Post-quarter end, the Company



expects to imminently receive a further cash injection from the Australian Government's R&D Rebate in relation to its overseas R&D expenditure, totaling approximately A\$3.3 million to support operational and clinical expenditure whilst closing out R&D advances for the 2023 financial year.

Recce Awarded A\$54.9m AusIndustry Advanced Overseas (R&D) Finding for Anti-Infective and Anti-Viral programs

The Company announced that the Australian Government awarded **A\$54,947,284 across the infectious disease portfolio** for its Synthetic Anti-Infective (**A\$43.7m**) and Anti-Viral (**A\$11.2m**) Research & Development (R&D) applicable expenditure by AusIndustry (a division of the Australian Government's Department of Industry, Innovation and Science).

This 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 (1 July 2022 to 30 June 2025).

It is one of the largest awarded in Australian history as a pillar of the R&D Tax Incentive Program administered by the Australian Government. This Finding does not constitute a grant, or an upfront payment of the amount awarded.

## **Operational Highlights**

Safety Committee Approves Faster Infusion Rate of 15 Minutes in Phase I/II UTI/Urosepsis Rapid Infusion Clinical Trial

The Company announced Independent Safety Committee approval for next cohort dosing at a faster infusion rate of 15 minutes of 3,000mg. Furthermore, the committee unanimously agreed R327 at an infusion rate of 30 minutes of 3,000mg is safe and well tolerated in male and female subjects with the next cohort of subjects to begin dosing imminently.

Receiving the committee's go-ahead to proceed with dosing R327 at a 15-minute infusion rate of 3,000mg is a positive indication of R327s advancement as a broad-spectrum anti-infective across the full spectrum of UTIs (simple, complicated and recurring) through to their all-out septic state 'Urosepsis'.

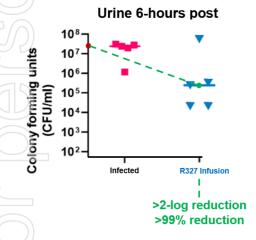
## First Subjects of Recruited Cohort Dosed Phase I/II UTI/Urosepsis Rapid Infusion **Clinical Trial**

Following independent safety committee approval, the Company announced that the first male and female subjects have completed dosing at the highest concentration of RECCE® 327 (R327) (3,000mg I.V.), within a fast infusion rate of 15- minutes in its Phase I/II UTI/Urosepsis clinical trial. With the study tracking to primary endpoints R327 at 3,000mg (double what was previously delivered over 30-minutes) over 15-minutes is the fastest infusion rate completed to date.

Committee is expected to review urine and plasma concentration data shortly with next steps to follow.

# Positive Escherichia coli UTI Animal Study Efficacy Data from Murdoch Children's Research Institute via intravenous infusion and new direct-to-bladder delivery

The Company announced positive efficacy data, with RECCE® 327 (R327) showing significant antibacterial activity against Escherichia coli (E. coli) urinary tract infections (UTI) by Murdoch Children's Research Institute in a physiologically relevant rat UTI model.



## Study 1 - Efficacy of R327 against E. coli UTI in a rat model

Study 1 resulted in over a >99% reduction (>2-log reduction) of E. coli UTI in a rat model. The study used 500 mg/kg dosing of R327 over a 1-hour infusion to test the efficacy of R327 treatment in a physiologically relevant rat UTI model. A reduction of bacterial load in urine at 6-hours post-infection (6phi) was observed.

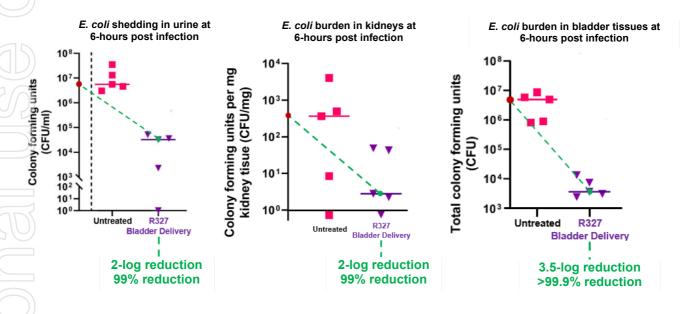
## Study 2 - Efficacy of R327 against E. coli UTI direct-to-bladder

Study 2 tested the efficacy of R327 against an E. coli UTI in a rat model-modified treatment protocol.

The dose was doubled from Study 1 to 1,000 mg/kg and given twice (at 2 hours and 4 hours post infection) for a total dose of 2,000 mg/kg, delivered via direct-to-bladder. Endpoints to assess efficacy were conducted at 6-hours post-infection.

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- Bacterial shedding of E. coli in the urine was measured, where a 2-log reduction (approx. 99% bacterial kill) for the R327 bladder delivery compared to the untreated control group.
- Bacterial burden of E. coli in kidney tissue was also analysed, with a 2-log (99% kill) reduction for R327 direct-to bladder delivery.
- Bacterial burden was analysed for E. coli in bladder tissue, with a bactericidal (>99.9% kill) 3.5-log and statistically significant reduction observed for the bladder delivery, compared to the untreated control group.

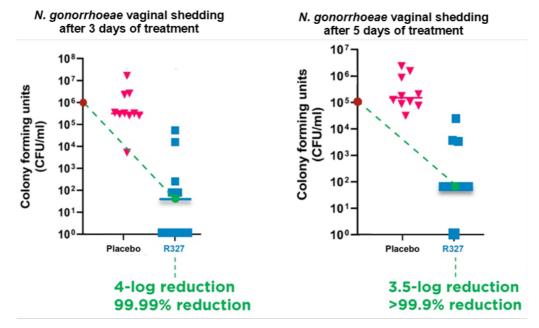


The fast I.V. infusions with ex vivo testing of participants urine containing R327 to kill E. coli and is progressing as planned. The study further investigates R327 as a viable treatment option for first patient presentation in both early stage (GP) and late stage (hospital) settings.

# Positive Neisseria gonorrhoeae Animal Model Efficacy Data from Murdoch Children's Research Institute - 4-log (99.99%) and 3.5-log (>99.9%) reduction

The Company announced positive efficacy of RECCE® 327 (R327) showing significant antibacterial activity against Neisseria gonorrhoeae (N. gonorrhoeae). The study was conducted by Murdoch Children's Research Institute to test the efficacy of R327 treatment against *N. gonorrhoeae* in a mouse vaginal infection model.

Groups of 10 mice were inoculated vaginally with N. gonorrhoeae. R327 was administered twice daily as IV bolus dose of 1,000mg/kg and after three days, the mice treated with R327 showed an approximate 4-log (99.99% reduction) reduction in bacterial shedding – significant bactericidal activity. After five days of treatment, R327 showed a 3.5-log reduction (>99.9% reduction) in bacterial shedding compared to the placebo-treated group.



#### Canadian Patent Granted for RECCE® Anti-Infectives

The Company announced the Canadian Patent Office has formally granted a new Patent Family 4 for Recce's anti-infectives "Process for Preparation of Biologically Active Copolymer" in Canada, expiry 2041.

The Granted Canadian Patent claims relate to RECCE® 327 (R327) and RECCE® 529 (R529), most notably:

- Process for preparation of RECCE® anti-infectives
- Use of R327/R529 for the treatment of disease, particularly in treatment of bacterial infections, viral infections and more
  - Specifically, further validating RECCE<sup>®</sup> anti-infectives from studies in Burn Wounds, Urinary Tract Infections, Gonorrhoea, Influenza, SARS-CoV2 and more
- Administration by oral, inhalation, transdermal delivery or by injection (into the bloodstream, intramuscular and/or intravenous)
- Administration may also be applied as an aerosol, gel, topical foam or ointment (or impregnated into a dressing for application to skin or mucous membranes for transdermal or transmucosal delivery)

## Brazil Trade Mark Accepted for RECCE® Anti-Infectives

The Company has received Trade Mark Registration acceptance for RECCE® from the Brazilian National Institute of Industrial Property.

The International Trade Mark Registration No. 927993422, formally assigns Brazilian Trademark No. 927993422 for the RECCE® mark, classified under the following class(es) and specification(s):

#### Class 5

- Antibiotics
- Antibiotics for human use
- Pharmaceutical preparations, namely mixed antibiotic preparations

#### Recce Presents at Ord Minnett Healthcare Forum

Recce Pharmaceuticals CEO, James Graham, presented at the Ord Minnett Healthcare Forum, attendees included institutional investors, Ord Minnett Wealth advisers and their highnet-worth clients. The Company's presentation can be found here.

### 2023 Annual General Meeting Conducted

The Company held its Annual General Meeting of shareholders on Monday, 8th November 2023. All resolutions were decided by way of poll and were passed with the exception of Resolution 1 which was not passed and was constituted as a 'first strike' for purposes of the Corporations Act 2001 (Cth).

## **Looking Ahead**

The Company is encouraged by the efficacy data received in this quarter for multiple indications and remains focused on completing its many active clinical trial objectives. The Company expects to imminently receive a significant R&D rebate for its R&D activities undertaken during last financial year both locally, and uniquely thanks to the recently awarded Advanced Finding Status, inclusive of activities overseas.

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

# **Appendix 4C**

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

#### Name of entity

Recce Pharmaceuticals Ltd

ABN

73 124 849 065

1.9

activities

Quarter ended ("current quarter")

(2,287,679)

December 2023

Consolidated statement of cash flows **Current quarter** Year to date (6 months) 1. Cash flows from operating activities 1.1 Receipts from customers 1.2 Payments for (3,603,346)(6,448,056)(a) research and development product manufacturing and operating (c) advertising and marketing (766, 765)(421,037)(d) leased assets (e) staff costs (350,277)(799,694)administration and corporate costs (225,548)(917,577)1.3 Dividends received (see note 3) 1.4 Interest received 29,232 33,401 1.5 Interest and other costs of finance paid 1.6 Income taxes paid 1.7 Government grants and tax incentives 2,281,150 2,378,245 1.8 2,148 3,148

2.	Cash f	flows from investing activities		
2.1	Payments to acquire or for:			
	(a) en	ntities	-	-
	(b) bu	ısinesses	-	-
	(c) pro	operty, plant and equipment	(7,520)	(106,270)
	(d) inv	vestments	-	-
	(e) int	tellectual property	-	-
	(f) oth	her non-current assets	-	-

(6,517,298)

Net cash from / (used in) operating

Consolidated statement of cash flows		Current quarter	Year to date (6 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)	(6,320)	(33,972)
2.6	Net cash from / (used in) investing activities	(13,840)	(140,242)

3.	Cash flows from financing activities		
J.	Cash hows from illianding activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	307,173	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	(78,716)	(561,356)
3.5	Proceeds from borrowings	-	800,855
3.6	Repayment of borrowings	(2,281,150)	(2,281,150)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
3.10	Net cash from / (used in) financing activities	(2,052,693)	9,104,523

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	8,362,773	1,561,578
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,287,679)	(6,517,298)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(13,840)	(140,242)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(2,052,693)	9,104,523

ASX Listing Rules Appendix 4C (17/07/20)

Consolidated statement of cash flows		Current quarter	Year to date (6 months)
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	4,008,561	4,008,561

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	4,008,561	5,647,501
5.2	Call deposits		
5.3	Bank overdrafts		
5.4	Other – Trust Account	-	2,715,272
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	4,008,561	8,362,773

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	1,186,786
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		

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 qu	arter 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)	(2,287,679)
8.2	Cash and cash equivalents at quarter end (item 4.6)	4,008,561
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	4,008,561
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	1.75
	Note: if the entity has reported positive net operating cash flows in item 1.9, answer iter figure for the estimated quarters of funding available must be included in item 8.5.	m 8.5 as "N/A". Otherwise, a

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: Yes

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: Yes. Further R&D rebates for FY2023 expected imminently. Significant R&D credits accrued since 1 July 2023 now backed by recently announced Australian Government Advanced Overseas R&D Finding awards a privileged position of future R&D repayment surety. It's expected the Company will take advantage of this status by drawing down on R&D credits accumulated this FY via R&D advances.

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: As above

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

- 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: 30/01/2024

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.
- 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.