ASX Announcement

Recce Pharmaceuticals
recce.com.au
ACN 124 849 065

Quarterly Cash Flow Statement & Operational Highlights

Highlights:

- **Successful, strongly supported capital raise of AUD $10.7 million – Shortfall of approximately AUD $0.3m fulfilled by Recce Directors and additional investors**
- **Phase I Clinical Trial Data Review Complete – RECCE® 327 achieved all primary study end-points, met international regulatory standards in data and showed RECCE® 327 to be safe & well tolerated**
- **Multiple Cohorts Dosed in Phase I/II (I.V.) UTI Clinical Trial across male and female subjects – RECCE® 327 (R327) safe and well tolerated at faster infusion rates**
- **Diabetic Foot Infection Clinical Trial – commenced dosing of patients at South West Sydney Limb Preservation and Wound Research Unit**
- **Phase I/II Burn Wound Infection Trial Stage 1 Complete - Bacterial infections successfully treated with RECCE® 327 in patients treated to date**
- **Multiple patients dosed with RECCE® 327 Gel (R327G) under TGA Special Access Scheme – Category A**
- **New Family 4 Patent granted for RECCE® Anti-Infectives by Australian Patent Office**
- **RECCE® Trademark Registered in Vietnam from the Intellectual Property Office of Vietnam, under Trademark Registration No. 1289603**
- **Further A$801,604 R&D Advance Received and Bonus Canadian R&D Rebate received**
- **Austrade Sponsorship for Recce to attend BIO Japan as part of Team Australia**
- **Abstract & Poster Presentation Published at the 2023 Military Health System Research Symposium (MHSRS)**
- **Delivered Opening R&D Address at the World Anti-Microbial Resistance Congress**

SYDNEY Australia, 20 October 2023: Recce Pharmaceuticals Ltd (**ASX:RCE**, **FSE:R9Q**) (the **Company**), the Company developing a New Class of Synthetic Anti-infectives, today released its September 2023 quarter results and operational highlights.

Financial Update

The Company ended the quarter with a cash balance of $8.36 million. Net cash outflows from operating activities were ($4.23 million), with Research and Development ($2.84 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 fees) was ($0.68 million).

Strongly Supported Capital Raise

The Company was pleased to announce it successfully completed a strongly supported raise of **AUD $10.7 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. **CEO James Graham, took up his full entitlement, investing a further AUD $102.7k into the Company.** Furthermore, the Company had announced a Shortfall under the Entitlement offer and received commitments totalling approximately AUD $0.3 million. Directors of the Company took a portion of the Shortfall, representing approximately 250,000 shares (**AUD $110k**), and will seek shareholder approval at the upcoming Annual General Meeting, to be held on the 8th November 2023.

Local and International R&D Rebates

The Company announced further non-dilutive funds from Radium Capital (Radium) for AUD $801,604 of Recce's future Research and Development (R&D) tax incentive. The advance payment of AUD $801,604 received from Radium Capital, represents an accountant verified proportion of its March-May FY23 R&D applicable expenditure. Furthermore, the Company was pleased to receive an international cash receipt of AUD $98,428.27 from the Government of Canada as part of its Scientific Research & Experimental Development (SR&ED) Tax Incentive program. This amount was the second rebate the Company has received from the Government of Canada.

Operational Highlights

Phase I Clinical Trial Data Review Complete

The Company announced it had received positive complete and independently verified results from its Phase I (R327-001) study of RECCE® 327 (R327) as an intravenous infusion formulation in 80 healthy male subjects. **R327 was found to be well tolerated with a good**

safety profile across all dose groups from 50 mg to 6,000 mg when administrated intravenously over one hour infusion.

The results showed a significant dose-dependent concentration of R327 in both the urine and the plasma, highlighting the potential of R327 as a potential treatment of sepsis and complicated/uncomplicated UTIs. Another positive, yet unexpected finding, was the **improvement of healthy human cells in the PK/P.D. analysis**, including indications of **improved kidney health from R327** as it was excreted from the body - no change in any chemistry parameter(s) to those dosed with R327 – with all kidney and liver functions appearing to be normal.

In concurrence with the Therapeutic Goods Administration clinical trial regulatory procedures, the study is closed and marked '**Complete'** with no '**Serious Adverse Events**' reported.

RECCE® 327 Phase I/II UTI/Urosepsis Rapid Infusion Clinical Trial

During the quarter, the Company provided multiple updates on its Phase I/II UTI/Urosepsis Rapid Infusion Clinical Trial.

Interim results show R327 was safe and well tolerated at two faster infusion rates (faster infusion rate than that of subjects in recently completed Phase I Clinical Trial) of 2,500mg and 3,000mg observed via intravenous administration in male and female participants (first female dosed with R327 safely) – with **no serious adverse events noted**. The study is tracking to primary endpoints, with an Independent Safety Committee reviewing the current cohort data, with subject recruitment for next cohort well underway.

UTI's are responsible for about 30% of all sepsis infections, defined as 'Urosepsis'[1]. R327's potential as a treatment option across the patient infectious disease journey (underlying infection>septic state) positions it for therapy in this area of unmet medical need. More information on this trial can be found at the Australia New Zealand Clinical Trial Registry under the trial ID ACTRN12623000448640.

[1] Qiang XH, Yu TO, Li YN, Zhou LX. Prognosis Risk of Urosepsis in Critical Care Medicine: A Prospective Observational Study. Biomed Res Int. 2016;2016:9028924. doi: 10.1155/2016/9028924. Epub 2016 Feb 3. PMID: 26955639; PMCID: PMC4756185.

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Diabetic Foot Infections Clinical Trial – Patient Dosing Commenced

The Company announced it had commenced dosing of patients at Liverpool Hospitals South West's Sydney Limb Preservation and Wound Research Unit with daily dose visitation of out-patient nurses in its Phase I/II Diabetic Foot Infections clinical trial – the largest Diabetic Foot Infection study underway in Australia at this time.

The Phase I/II clinical trial is a prospective, interventional study assessing the safety and efficacy of R327 as a topical broad-spectrum, dosed daily over 14 days as a potential topical anti-infective treatment for patients with mild skin and soft tissue diabetic foot infections.

Each year the High-Risk Foot Service (HRFS) at Liverpool Hospital manages approximately 800 patients presenting with complex foot disease, with over 80% occurring in people with diabetes. The study is supported by out-patient (at home) nurses trained in R327 Diabetic Foot Infection treatment protocols, ensuring daily dosing, wound health, while capturing a broadened patient population.

More information on this trial can be found at the Australia New Zealand Clinical Trial Registry under the trial ID ACTRN12623000056695.

New Australian Family 4 Patent Granted for RECCE® Anti-Infectives

The Company announced the Australian Patent Office had formally granted the first of Recce's new Patent Family 4 for RECCE's anti-infectives "Process for Preparation of Biologically Active Copolymer", expiry 2041.

This is the first of Recce's wholly owned Family 4 Granted, with Patent Cooperation Treaty Country (PCT) patent submissions in respective stages of review.

RECCE® Trademark Registered in Vietnam

The Company announced it had been issued Trademark Registration for RECCE® from the Intellectual Property Office of Vietnam.

The International Trademark Registration No. 1289603, has been formally assigned to the International Bureau (World Intellectual Property Organization) by the Office of Vietnam, for the use of the RECCE® mark.

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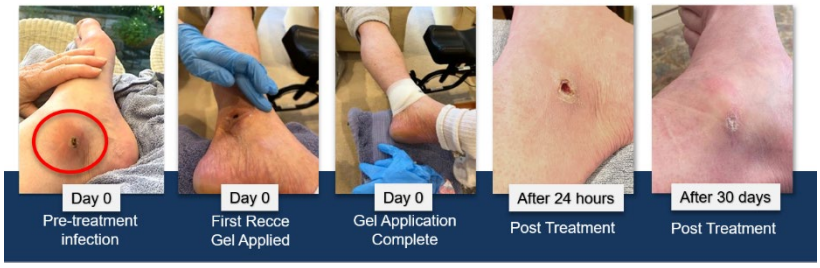
In 2020, Vietnam's pharmaceutical market was valued at approximately USD $10 billion, doubling in value since 2015; with the projected value reaching USD $16.1 billion in 2026. Antibiotic-resistance in Vietnam is amongst the highest in the world.

Multiple Patients Dosed under the TGA SAS – Category A

The Company had announced it had treated a total of five patients under the TGA Special Access Scheme – Category A with new RECCE® 327 Gel (R327G). R327G was used by a qualified medical practitioner across patients suffering antibiotic-resistant Gram-positive and Gram-negative bacterial infections. Such infections included (but not limited to): Necrotising fasciitis (flesh eating bacteria), Osteomyelitis (bone infection), talar avascular necrosis (death of bone tissue due to lack of blood supply) and complex skin structure bacterial infections.

All those treated with R327G indicated a positive clinical response in the treatment of multiple antibiotic-resistant infections. In some cases, with only one dosing application of R327G, the infection had clinically responded (no pre-treatment wound debridement was required). Patients treated with R327G were able to avert surgical intervention (commonly amputation in diabetic patients).



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The results shown in the case studies must be considered anecdotal; however, they were presented in the interest of the Company's continuous disclosure obligations and are not part of any present clinical trials. R327G is an experimental compound, not market approved for use in humans; safety and efficacy are to be determined by present clinical studies.

Disclaimer: Patients have been treated pursuant to the SAS-Category A; a notification pathway that can be accessed by health practitioners on behalf of a prescribing medical practitioner for patients who are seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment, and does not constitute a clinical trial[2].

Phase I/II Clinical Trial – Treatment of Burn Wound Infections Stage 1 Complete

The Company had announced it had completed the Data Analysis for its Phase I/II Topical clinical trial of R327 for the treatment of burn wound infections. All patients treated with R327 showed good indications of safety and tolerability to the compound with **no serious adverse events reported** among patients.

Clinicians reported visible reduction in bacterial infection within the first 24 hours of R327 treatment, with R327 demonstrating broad spectrum antibiotic activity against Gram-positive and Gram-negative pathogens (listed on the WHO Priority Pathogen list of antibiotic-resistant bacteria[3]), which are defined as multidrug-resistant and difficult to treat.

Recruitment has concluded for Stage 1 of the investigator-led clinical trial, and in the interest of accessing a greater patient population, clinical investigators are preparing a new protocol in line with progress objective of next stage 'Head-to-head' investigation. Stage 2 clinical trial is 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.

Austrade Sponsorship to attend BIO Japan 2023

The Company was sponsored by Australian Government Organisation, Austrade, to send a sponsored delegate to attend BIO Japan 2023 as part of Team Australia. This year's Australian Delegation was provided with subsidised travel costs and discounted registration fees. The registration fee covers one-on-one meetings and networking events with the world's leading biotech companies.

[2] https://www.tga.gov.au/sites/default/files/special-access-scheme-guidance-for-health-practitioners-and-sponsors.pdf
[3] https://www.who.int/news/item/27-02-2017-who-publishes-list-of-bacteria-for-which-new-antibiotics-are-urgently-needed

Opening R&D Address at World Anti-Microbial Resistance Congress 2023

Recce Pharmaceuticals, Non-Executive Director and Chief Medical Advisor, Dr. Alan W Dunton delivered the Opening R&D Address at the World Anti-Microbial Resistance Conference, positioning Recce as a sign of new hope in the fight against superbugs on the international stage. The presentation can be viewed here. Dr Dunton's presentation was titled: ***Breaking the Paradigm for New Anti-Infectives***

Separately, on the day, CEO James Graham along with other Key Opinion Leaders were part of a panel, led by President and CEO of Sepsis Alliance Thomas Heymann, on the topic of ***Sepsis and AMR – Raising Awareness to Save Lives.***

Dr Alan W Dunton

Left to right:
Thomas Heymann *(Sepsis Alliance);* ***Edie Stringfellow*** *(Centre for Global Health Innovation);* ***James Graham*** *(Recce Pharmaceuticals);* ***Mary Millard*** *(Sepsis Patient Advocate)*

Abstract & Poster Presentation at Military Health System Research Symposium

The Company announced it had received confirmation to publish a research Abstract and Poster presentation at the 2023 Military Health System Research Symposium (MHSRS). The Abstract & Poster publications was accompanied by an in-person, oral presentation by Dr John Prendergast, Executive Chairman of Recce Pharmaceuticals.

The abstract was titled: ***RECCE® 327: A Novel Synthetic Anti-infective for the Treatment of Antimicrobial-resistant Bacterial Sepsis Infections*** and the speaking session was focused on ***Antimicrobial Countermeasures for Wound Infections in Military Personnel***.

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The MHSRS is the United States (US) Department of Defence's foremost scientific meeting. It provides a venue for presenting new scientific knowledge particular to military specific focuses in research and development.

Annual Report 2023 Released

The Company released its Annual Report for the 2023 financial year. The report documents commercial, clinical, and regulatory highlights. The Annual Report can be viewed here.

Looking Ahead

The Company is focused on its updated clinical trial objectives and timelines, with priority placed upon getting its products to market expediently. The Company remains well placed to deliver upon its overall goals and objectives over the time 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	September 2023

Consolidated statement of cash flows		**Current quarter**	**Year to date (3 months)**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(2,844,710)	(2,844,710)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(345,728)	(345,728)
	(d) leased assets	-	-
	(e) staff costs	(449,417)	(449,417)
	(f) administration and corporate costs	(692,029)	(692,029)
1.3	Dividends received (see note 3)		-
1.4	Interest received	4,169	4,169
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	97,095	97,095
1.8	Other	1,000	1,000
1.9	**Net cash from / (used in) operating activities**	**(4,229,619)**	**(4,229,619)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(98,750)	(98,750)
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter	Year to date (3 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)	(27,652)	(27,652)
2.6	**Net cash from / (used in) investing activities**	**(126,402)**	**(126,402)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	10,715,272	10,715,272
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	123,728	123,728
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(482,639)	(482,639)
3.5	Proceeds from borrowings	800,855	800,855
3.	Repayment of borrowings	-	-
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**	**11,157,216**	**11,157,216**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	1,561,578	1,561,578
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(4,229,619)	(4,229,619)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(126,402)	(126,402)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	11,157,216	11,157,216

Consolidated statement of cash flows		Current quarter	Year to date (3 months)
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**8,362,773**	**8,362,773**

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	5,647,501	5,647,501
5.2	Call deposits		
5.3	Bank overdrafts		
5.4	Other – Trust Account	2,715,272	2,715,272
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**8,362,773**	**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	676,634
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)	(4,229,619)
8.2	Cash and cash equivalents at quarter end (item 4.6)	8,362,773
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	8,362,773
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	1.98

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: 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. R&D Rebate submitted - significant net benefit from anticipated receipt during present quarter

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

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: 20/10/2023 .....

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.