ASX Announcement

Recce Pharmaceuticals
recce.com.au
ACN 124 849 065

Quarterly Cash Flow Statement & Operational Highlights

Highlights:

- **Strong cash position of $20.87 million**
- **Topical Phase I/II Clinical Trial began and was registered on Australia New Zealand Clinical Trial Registry**
- **R327 Sinusitis efficacy in Special Access Scheme Category A human case**
- **>99.9% effective against full suite of ESKAPE pathogens – only known antibiotic in clinical development efficacious against all ESKAPE pathogens**
- **R327 advances to Stage 2 in Australian government SARS-CoV-2 Program**
- **R327 – Demonstrates World First Multiple Mechanisms of Action**

SYDNEY Australia, 30 July 2021: Recce Pharmaceuticals Ltd (**ASX:RCE**, **FSE:R9Q**), the Company developing New Classes of Synthetic Anti-infectives, today released its June 2021 quarter results and operational highlights.

Financial Update

The Company ended the quarter with a cash balance of $20.87 million. Net cash out-flows were ($1.99 million), significantly offset by R&D rebates, grants and other state/federal initiatives. Research and Development ($1.03 million) was the largest item of expenditure. Payments to related parties (Executive & Director fees) was ($0.342 million).

Operational Highlights

Topical Phase I/II Clinical Trial began and was registered on Australia New Zealand Clinical Trial Registry

Phase I/II Topical Burns Study in Humans was registered on the Australia New Zealand Clinical Trials Registry (ANZCTR) under the trial ID ACTRN12621000412831: *'Proof of Concept Study of RECCE 327 Topical Antibiotic Therapy for Infected Burn Wounds in Adults'*.

Sinusitis Study Activity (*in-vivo*)

The Company announced **positive** sinusitis animal study data against the Gram-positive bacterium *Streptococcus pneumoniae (S. pneumoniae)*. The study was conducted by an independent Contract Research Organisation, to assess dose-dependency of RECCE compounds *in-vivo* against *S. pneumoniae* in a mouse model of acute bacterial rhinosinusitis infection.

Special Access Scheme Category A – A Patients Journey

Building on *in-vivo* safety & efficacy, the Company reported a positive human clinical response in a patient following dosing of R327, via nasal passage, against multi drug resistant, Gram-negative *Pseudomonas aeruginosa (P. aeruginosa)* pursuant to the Therapeutic Goods Administration Special Access Scheme - Category A (SAS - Category A).

R327 is **not market approved** for use in humans. Further clinical testing is required to evaluate safety and efficacy.

An ESKAPE Pathogen Company

R327 repeatedly achieved a **>99.9% bacterial reduction** against the full suite of ESKAPE pathogens, within hours of exposure. R327's Broad Spectrum antibiotic showed uniquely comparable efficacy against the hypermutated ESKAPE superbugs, including Multi-Drug Resistant forms – a current market challenge of all existing antibiotics.

R327 was further tested against two WHO global priority pathogens carbapenem resistant *Escherichia coli (E. coli* CRE*)* and multi drug resistant *Neisseria gonorrhoeae (N. gonorrhoea* MDR*),* demonstrating similarly high levels of efficacy.

The Company is the only known antibiotic in clinical development efficacious against all ESKAPE pathogens globally.

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SARS-CoV-2

The Company further advances its SARS-CoV-2 studies, completing Stage 1B and receiving a qualified recommendation to **advance to Stage 2 of the Program for further testing** at a government research institution. Stage 1B supported and extended findings of its previous Australian SARS-CoV-2 studies and allowed the half maximal inhibitory concentration (IC50) of 2,046ppm and cytotoxicity (CC50) of 5,108ppm of R327 to be determined.

Further testing must be completed to determine whether R327 will show an inhibitory effect against the SARS-CoV-2 virus without associated toxicity.

World First Multiple Mechanisms of Action

The quarter saw the Company announce further insight into R327's Mechanism of Action (MoA). The MoA was found to be *'unlike that of any antibiotic seen before'* with multiple mechanisms identified in independent study.

The study was performed by independent, world leaders in bacterial Mechanism of Action analysis and antibiotic profiling.

Key takeaways from the study were as follows:

- **R327 rapidly and irreversibly shuts down cellar energetics** (ATP production) – primary MoA
- **R327 affects the assembly of bacterial cell division** complex, components that require cellular energy to remain assembled, confirming its ability to disrupt cellular bioenergetics
- R327 results in the decreased formation of the bacterial cell division complex into ring-like structures (Z-rings) in a concentration dependent manner
- **R327 permeabilizes the cell membrane or alter the integrity of the outer membrane** of *E. coli* cells – intended activity without toxicity
- At higher concentrations **and subsequent to ATP shut down cell lysis (bacterial bursting due to their uniquely high internal pressures) can occur as a further mechanism of action**
- R327 rapidly and irreversibly bactericidal to slow-growing, quiescent or stationary phase *E. coli* cells in addition to actively dividing *E. coli* cells

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- Within a minute, the highest concentration of R327 used, 5x minimum inhibitory concentration (MIC), was observed to reduce viable cell counts reported as cell forming units per millilitre of culture (CFU/ml) 100-fold (>1x107 to 1x105 at timepoint 0)
- **Current antibiotics rarely retain bactericidal activities against nondividing or stationary phase bacterial cells**; however, R327 showed remarkable activity against slow-growing bacteria thereby indicating potential antibacterial activity in biofilms
- In comparison to ampicillin and ciprofloxacin, **R327 is able to outperform both of these antibiotics** in bactericidal activity (as measured by viable cell counts) against stationary cells

These findings, elucidating R327's MoA, saw acceptance of invitation to present at the World Microbe Forum following confirmation to publish an Abstract in the 2021 program. The presentation was in the format of an iposter (digital poster).

Looking Ahead

The Company would like to thank its shareholders and wider network for their ongoing support. Throughout the ongoing pandemic, Recce maintains its focus on maximising the potential of their therapeutic compounds to address the global unmet medical need of antibiotic resistance and emerging viral pathogens.

With a strong cash position and increasingly positive data, the Company is well placed to continue to deliver on its globally relevant objectives over the time ahead.

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

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About Recce Pharmaceuticals Ltd

Recce Pharmaceuticals Ltd (ASX: RCE, FSE: R9Q) is pioneering the development and commercialisation of New Classes 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 is unique and comprised of broad-spectrum synthetic polymer antibiotics RECCE® 327, RECCE® 435, and RECCE® 529 for viral infections with unique mechanisms of action against hyper-mutation on bacteria and viruses, respectively.

Patented lead candidate RECCE® 327 as an intravenous therapy, is being developed for treatment of serious and potentially life-threatening infections including sepsis due to Gram-positive and Gram-negative bacteria including their superbug forms. Recce's new antibiotic compound, RECCE® 435, has been formulated for oral use.

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 only synthetic polymer and sepsis drug candidate in development.

Recce wholly owns its automated manufacturing, ready to support first-in-human clinical trials. Recce's anti-infective pipeline seeks to exploit the unique capabilities of RECCE® technologies targeting synergistic, unmet medical needs.

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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 2021

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	(1,036,691)	(6,267,565)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	-	-
	(d) leased assets	-	-
	(e) staff costs	(358,886)	(1,412,024)
	(f) administration and corporate costs	(632,209)	(2,082,186)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	32,282	105,757
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	1,566,031
1.8	Other (provide details if material)	-	105,107
1.9	**Net cash from / (used in) operating activities**	**(1,995,504)**	**(7,984,880)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(46,223)	(76,008)
	(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)	(13,693)	(36,814)
2.6	**Net cash from / (used in) investing activities**	**(59,916)**	**(112,822)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	27,950,000
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	106,276
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	(1,718,675)
3.5	Proceeds from borrowings	-	-
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**	**-**	**26,337,601**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	22,928,442	2,633,123
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,995,504)	(7,984,880)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(59,916)	(112,822)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	26,337,601

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**	**20,873,022**	**20,873,022**

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	20,873,022	20,873,022
5.2	Call deposits		
5.3	Bank overdrafts		
5.4	Other (provide details)		
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**20,873,022**	**20,873,022**

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	342,456
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)	(1,995,504)
8.2	Cash and cash equivalents at quarter end (item 4.6)	20,873,022
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	20,873,022
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	10.46

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: 30 July 2021 .....

Authorised by: 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.