

ASX Announcement

Quarterly Cash Flow Statement & Operational Highlights

Highlights:

- Strong cash balance of A\$25.68 million after successful capital raising
- Phase I human clinical trial to evaluate RECCE® 327 (I.V.) in healthy subjects at leading clinical research organization, Adelaide's CMAX
- SARS-CoV-2 domestic and international studies on-track
- Presented positive oral data on New RECCE® 435 against *H. pylori*, without toxicity
- *H. pylori* study agreement with Murdoch Children's Research Institute
- Secured AusIndustry Grant \$37,508 + GST with \$50,000 more upon milestones
- Expanded management and advisory teams with CEO, Board of Directors, Clinical Advisory Committee and Chief Scientific Officer appointments.

Sydney Australia, 21 October 2020: Recce Pharmaceuticals Ltd (ASX: RCE) (Company), the Company developing New Classes of Synthetic Anti-infectives, today reported its 30 September 2020 quarter results and operational highlights.

Financial Update

The Company ended the quarter with cash reserves of **\$25,687,906** after a well supported placement of \$1.30 per share. Cash out-flows from operations were \$3.3 million with investment in research and development (\$2.5m) the main source of expenditure during the period; \$0.370m to related parties (executive & director fees). The Company is well funded to advance its clinical and commercial programs.

The Company also received a \$37,508 grant as part of the Entrepreneurs' Program run by the Department of Industry, Science, Energy and Resources. The funds will be go towards costs associated with the RECCE® 327 in the SARS-CoV-2 antiviral screening program with a further \$50,000 to be paid on achieving development milestones.



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Operational Highlights

Phase I Clinical Trial Update

The Phase I clinical study of its lead compound, RECCE® 327 is being conducted at South Australia's CMAX Clinical Research. The trial is progressing as planned with significant volumes of RECCE® 327 and placebo produced to specification for the study at the Company's manufacturing facility in Macquarie Park Sydney.



Above: RECCE® 327 and placebo samples for the Phase I study.

The Phase I study will assess the safety and tolerability of RECCE® 327 through intravenous infusion in healthy subjects as a single ascending dose.

SARS-CoV-2 International Studies

University of Tennessee researchers evaluated RECCE® 327 and RECCE® 529 compounds in an *in-vitro* respiratory organoid model. RECCE® 327 and RECCE® 529 showed concentration-dependent reductions in the SARS-CoV-2 virus. In a separate but related study, concentrations of RECCE® 327 and RECCE® 529 were tested and further indicated an excellent toxicity profile (<0.25%) on Vero (monkey) cells. U.S. researchers recommended advancing research of both compounds, prompting the Company to secure testing in a gold-standard *in-vivo* COVID-19 infection study in animals (ferrets) with data on-track within the calendar year.

CSIRO/Doherty Institute SARS-CoV-2 Australian studies

A study of RECCE® 327 against SARS-CoV-2 (COVID-19) has been completed according to protocol. Results are expected for reporting in November.

Chief Executive Officer

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New oral formulation – RECCE® 435

RECCE® 435 is a broad spectrum synthetic polymer antibiotic formulated for oral use. In a recent study, RECCE® 435 showed dose-dependent efficacy against *Helicobacter pylori* (*H. pylori*) bacteria isolated from a patient with a duodenal ulcer compared to control vehicle in independent study model in rats. In a separate and independent oral dosing study, RECCE® 435 yielded no observed toxicity with favourable weight gain throughout.

Murdoch Children's Research Institute (MCRI) has since entered agreement with the Company to conduct a range of pre-clinical studies assessing the potential of RECCE® 435 for the treatment of *H. pylori* infections. The program is led by Professor Phil Sutton and carried out by the Mucosal Immunology Group at the MCRI, Royal Children's Hospital.

Board and Management

During the reporting period, the Company strengthened its management and advisory teams with a number of important appointments.

Dr. Alan W Dunton (M.D.) – Non-Executive Director

Dr. Dunton joined the Board as an independent Non-Executive Director and member of the Company's Audit & Risk/Remuneration & Nomination Committees.

Dr. Dunton has led clinical research development efforts and advanced drug candidates including a number of blockbuster antibiotics, through regulatory review and commercialisation at Fortune 500 companies including Johnson & Johnson and Roche.

Professor Phillip Sutton – Clinical Advisory Committee & Head of *Helicobacter pylori* program

Professor Sutton joined as Head of the *Helicobacter pylori* stomach development program.

Professor Sutton leads the Mucosal Immunology Group at the Murdoch Children's Research Institute in Victoria, Australia and has more than 30 years of research and industry experience having served as the former Head of Immunology at CSL Limited in Melbourne.

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Recce Appointments

The Company further appointed James Graham as Chief Executive Officer and Michele Dilizia as Chief Scientific Officer. Both have been with the Company since inception and will continue their roles as members of the Board. Michele will continue her significant contribution to advancing our important research, clinical collaborations and in-house research programs.

The Board and management remain focused and are moving as quickly as possible to take full advantage of our leadership in the global race to develop new therapies and create long-term shareholder value.



Dr. John Prendergast
Non-Executive Chairman
Recce Pharmaceuticals

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

Chief Executive Officer

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About Recce Pharmaceuticals Ltd

Recce Pharmaceuticals Ltd (ASX: RCE) 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 and 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 has been developed for the treatment of blood infections and sepsis derived from *E. coli* and *S. aureus* 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.

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.

Chief Executive Officer

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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

73 124 849 065

Quarter ended ("current quarter")

September 2020

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
1. Cash flows from operating activities			
1.1 Receipts from customers		42,500	42,500
1.2 Payments for			
(a) research and development		(2,460,711)	(2,460,711)
(b) product manufacturing and operating costs		-	-
(c) advertising and marketing		-	-
(d) leased assets		-	-
(e) staff costs		(369,671)	(369,671)
(f) administration and corporate costs		(525,654)	(525,654)
1.3 Dividends received (see note 3)		-	-
1.4 Interest received		1,685	1,685
1.5 Interest and other costs of finance paid		-	-
1.6 Income taxes paid		-	-
1.7 Government grants and tax incentives		-	-
1.8 Other (provide details if material)		-	-
1.9 Net cash from / (used in) operating activities		(3,311,852)	(3,311,852)
2. Cash flows from investing activities			
2.1 Payments to acquire or for:			
(a) entities		-	-
(b) businesses		-	-
(c) property, plant and equipment		-	-
(d) investments		-	-
(e) intellectual property		-	-
(f) other non-current assets		-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
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)	-	-
2.6	Net cash from / (used in) investing activities	-	-

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	27,950,000	27,950,000
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	94,785	94,785
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(1,678,150)	(1,678,150)
3.5	Proceeds from borrowings	-	-
3.6	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	26,366,635	26,366,635

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	2,633,123	2,633,123
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,311,852)	(3,311,852)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	26,366,635	26,366,635
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	25,687,906	25,687,906

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 \$A'000	Previous quarter \$A'000
5.1	Bank balances	25,687,906	25,687,906
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)	25,687,906	25,687,906

6.	Payments to related parties of the entity and their associates	Current quarter \$A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	370,803
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 <i>Note: the term "facility" includes all forms of financing arrangements available to the entity.</i> <i>Add notes as necessary for an understanding of the sources of finance available to the entity.</i>	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
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	\$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(3,311,852)
8.2	Cash and cash equivalents at quarter end (item 4.6)	25,687,906
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	25,687,906
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	7.76
<i>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.</i>		
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:	
<i>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.</i>		

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.

21/10/2020

Date:

By the Board

Authorised by:
(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.