Recce
Targeting Superbugs
recce.com.au
ACN 124 849 065

# ASX ANNOUNCEMENT

3 May 2016

## Recce: The Way Forward

- **RECCE® antibiotic 327 has begun the FDA process towards human trials.**
- **Recce estimates presenting its IND application to the FDA, end of Financial Year 2017**

Recce Ltd (ASX: RCE) the developers of a new class of drugs targeted at antibiotic and anti-cancer human applications, is pleased to provide an update on its activities.

The Company is focused upon obtaining approval of RECCE® antibiotic 327 to IND status by the Food & Drug Administration (FDA) of USA.

During the process, the FDA's examiners expect Recce to have submitted satisfactory data to them, in three areas: EFFICACY, SAFETY, and CHEMISTRY.

Recce is now pleased to update its progress:

- The Perth laboratory will produce RECCE® antibiotic 327 for tests of EFFICACY (e.g. tests in mice against infections caused by superbugs; the tests will take about 15% of the $1,215,000 budgeted in Recce's prospectus for "overseas animal safety/efficacy tests" - and take place over about 6 months);

- Reassuringly, within Recce's laboratory in Perth, the preparation of RECCE® antibiotic 327 has been repeated (including all quality assurance checks) by a technician who was not associated with the invention;

- This technician will now initiate the product's pilot-manufacture in a laboratory in Boston, USA where essential infrastructure, raw materials and proximity to the FDA are much more available than in Australia; this initiation is estimated to take about 3 months – and completion of the automated pilot-plant (for which tenders are currently being called), about a further 9 months;

- Recruitment of a chemical engineer, and assistant in the USA, both by mid-June 2016; they will ensure that the final product is produced in the pilot-plant to 'name-plate' standard, and continue to refine the already highly economical manufacture process of a little over 1 hour;

- The laboratory in Boston will be set-out and established at Good Manufacturing Practice (GMP) standards – and in order to aid Recce's progress to approval, it is proximate to the FDA;

- At a compulsorily higher standard for safety (than efficacy), the Boston pilot-plant will produce RECCE® antibiotic 327 for tests of SAFETY (consuming about 60% of the budget, over approximately 1 year). This comprises multiple, separate, acute and chronic, detailed tests in rats and other animals to reveal dosing and pharmacological patterns of action of RECCE® antibiotic 327;

- In cooperation with Recce's expert consultants in Boston, Recce will present and negotiate re all data for IND approval – the "passport" for subsequent testing of RECCE® antibiotic 327 in humans;

- During this process, CHEMISTRY will also be presented to the FDA, regarding the manufacturing of RECCE® antibiotic 327. This chemistry will include stability and formulation data, and will consume about 10% of the budget;

- Contingency will be made, equal to approximately 15% of the budget, as the FDA is quite likely to request additional testing than already undertaken by Recce for its presentation to the FDA.

Our recent financial reports have confirmed that all financial estimates made in the prospectus have provided a practical guide to future budgets – and hence, for Recce's objective of presenting the IND application to FDA, end of financial year 2017.

For further information please visit www.recce.com.au or contact:


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**About Recce Ltd**

Recce Ltd (ASX: RCE), led by Dr Graham Melrose, is a world-leader in synthetic-polymer antibiotics. RECCE® antibiotics have been synthesized by an extremely simple and economic method.

RECCE® antibiotics have shown in laboratory tests that they have continued activity against bacteria including superbugs, even after repeated use.

Recce is positioned to achieve milestones in both pre-clinical trials for FDA purposes and the development of a pilot-plant for automated manufacture of RECCE® antibiotics.

The discovery of RECCE® antibiotics 327's capabilities against cancer (as well as bacteria-superbugs) has greatly increased the value of the Company's technology, especially in view of synergism between the anti-cancer and antibiotic properties.

Recce has granted patents in Australia, United States, Europe, Japan and China – giving it legal monopolies and potential financial returns from manufacture and distribution in some 80% of the world's pharmaceutical markets.