Recce
Targeting Superbugs

recce.com.au
ACN 124 849 065

ASX Announcement

Operational Update

SYDNEY, Australia – 10 April 2017: Recce Limited (ASX: RCE), a pre-clinical-stage pharmaceutical company engaged in the development of a new class of synthetic antibiotics, provides an update on the significant pre-clinical and operational achievements over the past few months.

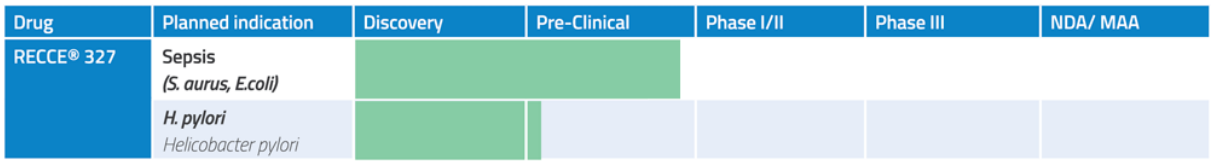
FDA Investigational New Drug (IND) Application on schedule

Central to the Company's strategy is to move RECCE® 327, the lead candidate drug, into human clinical trials as fast as possible. Work to complete the IND application to the US Food & Drug Administration (FDA) for permission to initiate a Phase 1a study in humans is progressing to schedule. Recce expects to submit this application as previously indicated around the end of July this year.

Financial

Recce is currently running some $990k under budget as at the end of the first quarter of 2017, with $1.66 million cash at bank as at 31 March 2017. This is primarily due to changes in the design and timing of various studies, plus minimisation of administrative expenses in line with the Company's aim of minimising costs whilst investing in building a highly valuable business.

RECCE DEVELOPMENT PROGRAMS



Estimated timelines/indications are subject to changes in development plans and regulatory requirements/clarifications
MAA – Marketing Authorisation Application NDA – New Drug Application

The IND submission will be based on a data package generated from pre-clinical animal studies completed and currently underway. Recce is working with a leading US pre-clinical and clinical trial group to support the design of the Phase 1a study which is designed to measure safety of RECCE® 327 in humans.

Promising pre-clinical data

The Company is very encouraged by recent results (as well as many in the past) which indicate RECCE® 327:

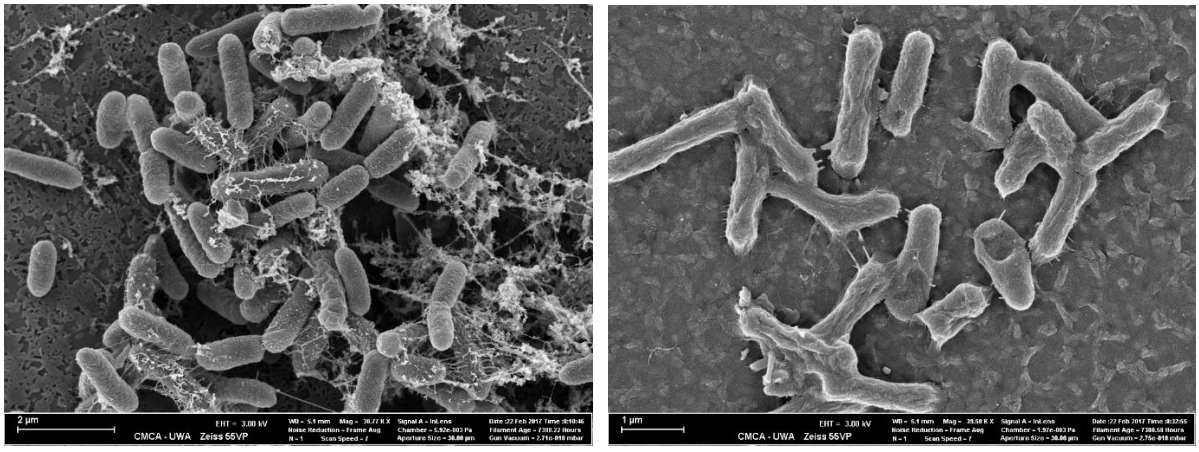
- Does not cause healthy cells to mutate
- Destroys Gram positive and Gram negative bacteria
- Acts against bacteria in both normal and mutated superbug forms – with the same ease
- Causes no adverse side effects in healthy cells
- Has an acceptable therapeutic dosing window

Pre-clinical studies move to large animal models

The Company has consolidated its focus and resources into developing its lead compound as a treatment for sepsis, as the first indication. Having already completed a series of studies of RECCE® 327 in mice, R&D has now progressed to include studies in larger animals. Initial data, reported to the ASX last month, indicate RECCE® 327 is well tolerated in a larger animal (dog) model administered via a drip application (rather than by a single injection).

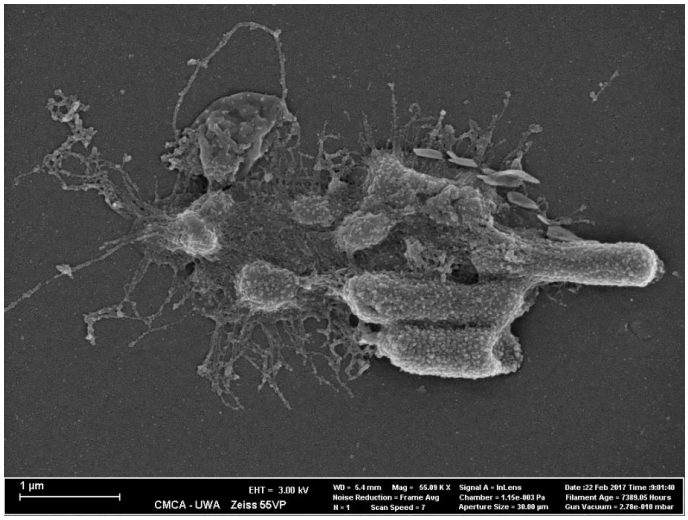
Our synthetic candidate antibiotic in action

In March, microscopy images of RECCE® 327 destroying *Escherichia coli* Gram-negative bacteria were captured by University of Western Australia scientists. The images reinforce the claims behind Recce's patents and contribute towards further understanding of the unique mode of action of the compound series.



Above left: 0 minutes - *E. coli* cells are healthy, smooth and intact.

Above right: 20 minutes – Significant cell membrane weakening and disruption



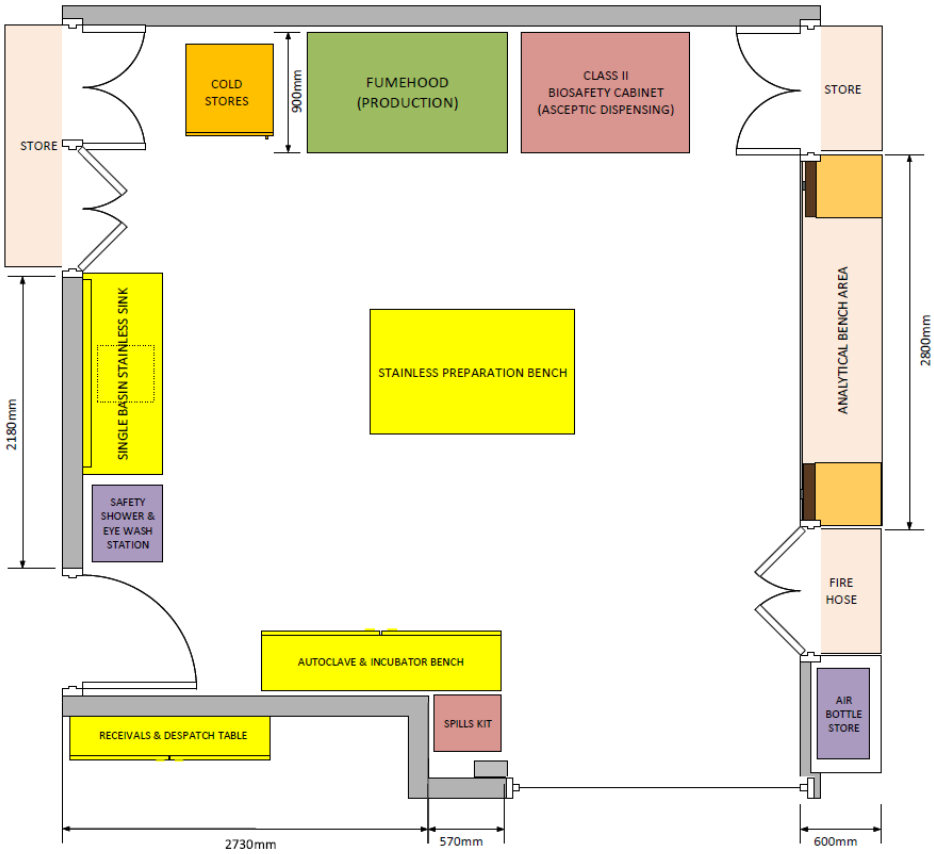
Left: 3 hours – Shows cell lysis and bacteria are destroyed

***E. coli* cells (10e6 cfu/ml) having their outer membrane weakened – and finally collapsing from treatment with RECCE® 327 (1000 ppm)**

Operations and manufacturing

The upgrade and quality-maintenance of Recce's Perth facility overseen by Senior Chemist and Quality Manager Dr Ward has been undertaken. Completed work includes implementation of new systems and processes to comply with pre-clinical and early clinical standards, which will be necessary for our IND application. The changes will allow multiple batch production runs. Importantly it will enhance our quality procedures, designed to enable reproducibility of the existing production process.

Construction of the Company's new facility in Sydney is also progressing on time and on budget. It is budgeted that the pilot-manufacture facility which was formally initiated late last year, will be delivered for around $300k using primarily 'off-the-shelf' equipment, commonly used in the pharmaceutical industry and recognized by global regulators.



Above: teaser of the pilot-manufacture facility layout currently under construction

The pilot-manufacture facility is on track to be producing product in early July to human clinical trial standards as determined by the US FDA. Documentation demonstrating the standards of the facility will form a key part of the IND.



Above: Macquarie Park facilities trialling drip bag dispenser in preparation for human applications

Recce's Sydney facility will become the primary short to medium term production site to support human clinical trials. The Perth facility will maintain its production capabilities and will operate as Recce's primary research centre.

Personnel

Recce has further expanded its technical capabilities with another key appointment. We are pleased to welcome highly skilled microbiologist Allan Rix, who has previously worked at global pharmaceutical companies Cochlear and Pfizer, and will start work with Recce in mid-April, taking responsibility for regulatory compliance and quality.

Favourable legislative environment globally

The World Health Organisation (WHO) recently published a priority list of antimicrobial resistant bacteria as a signal to world authorities to focus resources on urgently addressing this major problem. For Recce, which has advanced many programs through pre-clinical testing, including against some of the bacteria noted, this means the Company is well placed to take advantage of these ever expanding opportunities. Recce has already demonstrated efficacy against 7 of the top 12 bacterial threats identified and priority-categorised by the World Health Organisation:

Priority 1: CRITICAL	RECCE 327
▪ Pseudomonas aeuginosa, carbapenem-resistant	✔ 1
▪ Enterobacteriacae, carbapenem-resistant, ESBL-producing	✔ 2
▪ Acinetobacter baumannii, carbapenem-resistant	Not tested
Priority 2: HIGH	
▪ Enterococcus faecium, vancomycin-resistant	✔ 3
▪ Staphylococcus aureus, methicillin-resistant, vancomycin-intermediate and resistant	✔ 4
▪ Helicobacter pylori, clarithromycin-resistant	✔ 5
▪ Neisseria gonorrhoeae, cephalosporin-resistant, fluoroquinolone-resistant	✔ 6
▪ Campylobacter spp., fluoroquinolone-resistant	Not tested
▪ Salmonellae, fluoroquinolone-resistant	Not tested
Priority 3: MEDIUM	
▪ Streptococcus pneumoniae, penicillin-non-susceptible	✔ 7
▪ Haemophilus influenzae, ampicillin-resistant	Not tested
▪ Shigella spp., fluoroquinolone-resistant	Not tested

1. Active in vitro against Recce's own superbug of this bacterium; 2. Active in vivo against a member of this family CRE E. coli; 3. Active in vitro against a very closely related species, Enterococcus faecalis, Vancomycin resistant; 4. Active both in vitro and in vivo against MRSA, Methicillin-resistant Staphyloccocus aureus; 5. Active both in-vitro and in vivo against three strains (2 of which were superbugs); 6. Active in vitro against the normal bacterium (superbug form unavailable); 7. Active in vitro against related superbug Klebsiella pneumoniae

Potential for extended production and marketing exclusivity

Recce's focus on its primary drug RECCE® 327, for the treatment of high priority infectious diseases, means it is well positioned to take advantage of an increasingly supportive legislative environment.

Discussions with Recce's FDA consultants and patent attorneys as part of preparation of the IND application have confirmed key opportunities, representing up to 10 years' extended global production and marketing exclusivity for Recce, including access to a Fast Track review process.

This follows other developments including the establishment of the Generating Antibiotics Incentives Now (GAIN) Act in the US which seeks to activate the development of new antibiotics. The GAIN Act gives an extra five years of patent exclusivity to new antibiotics that treat serious or life-threatening illnesses.

A further five years market exclusivity is also available for molecules that the FDA defines as a 'New Chemical Entity' (NCE). Additionally, the FDA provides a framework to award 'Expedited Review Status'. Recce believes it will be eligible to benefit from these additional advantages.

United Nations against antimicrobial resistance

In addition to the WHO proclamation, the United Nations has formed an interagency group to co-ordinate the global fight against antimicrobial resistance. This comes after the historic agreement in September 2016 when 193 countries at the UN General Assembly agreed to work towards combating antimicrobial resistance. By forming the interagency coordination group on antimicrobial resistance, the UN is acknowledging this is not only a public health problem in its own right, but an issue that also undermines the attainment of other sustainable development goals - everything from education to economic growth to protecting the ecosystem.

Recce in the news

Our work to develop new antibiotic treatments continues to be recognised in Australia and internationally. Recent media coverage has reinforced the urgency and importance of our work.

The Australian – "Australia's Recce strives for immune-proof super-antibiotic"
The West Australian – "WA tests synthetic antibiotic"
S&P Global – "Small companies play big role in search for superbug killers"

Follow our progress

Recce is committed to maintaining consistent and transparent communications with all shareholders and the market. The Company encourages shareholders and interested parties to follow its progress and to register to receive regular updates via its website *http://www.recce.com.au*. Recce continues to make tremendous progress and looks forward to achieving further positive progress in coming months.

Dr Graham Melrose
Executive Chairman
April 2017