Biotech Daily

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Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Recce Pharmaceuticals

By TIM BOREHAM

ASX code: RCE

Share price: 27.5 cents

Shares on issue: 107,129,919*****

Market cap: $29.5 million; (*$36.6 million post-raising)

Chief executive officer (executive director): James Graham

Board: Dr John Prendergast (chairman), Dr Graham Melrose (chief research officer), Michele Dilizia, James Graham, Dr Justin Ward

Financials (year to June 30 2019): revenue nil, loss of $2.8 million (previously $1.7 million deficit), cash of $403,384 (previously $679,719)*****

***** Shares on issue and cash on hand are ahead of this week's placement of 26,032,478 shares that raised $6.76 million.

Major identifiable holders: Dr Graham and Olga Melrose 28%, Vesty Superannuation 4.3%, James Graham 4%, Foord Asset Management 3.9%.

If there's one reason to fear going into hospital a bit off color and emerging seriously ill, it's the strains of superbugs causing havoc in our healing institutions.

Pumping patients with traditional antibiotics isn't working, because the microscopic blighters have a habit of morphing and developing resistance.

Locally, the problem has been recognized by the Australian Pharmaceutical Benefits Advisory Committee, which this month recommended that repeat antibiotic prescriptions be banned.

Federal Health Minister Greg Hunt is pondering the proposal.

Recce itself is tackling sepsis, a life-threatening inflammation that spreads through the body via the blood as a result of infection. Sepsis is frequently caused by bacteria including Staphylococcus aureus (Golden Staph) and Escherichia coli (E coli) but can also be caused by fungi and viruses.

Recce's great white hope is a synthetic broad-spectrum antibiotic called Recce-327, which has so far proved promising in animal testing.

To further the cause, the company has just raised $6.76 million in a placement.

A problem that really bugs us

The sobering stats show that sepsis is a leading cause of death in intensive care units and rates in the top 10 hospital mortalities globally. The bug accounts for two percent of hospitalizations and 17 percent of hospital deaths, which just goes to show that hospitals are a dangerous place to be.

Someone in the world dies from sepsis every two minutes, while in the US it accounts for 270,000 deaths a year and costs the health system $US24 billion ($35 billion) a year.

Recce executive director James Graham notes the company has had positive results with seven of the 12 of the world's deadliest bacterial diseases, with the remaining five simply too dangerous to test.

"We aim to be the first approved drug for sepsis as a lead indication, given the unmet clinical need," he says.

Mr Graham says Recce's circumstances have changed from spruiking its message to being actively courted by hospitals and regulators (the former seeking compassionate use arrangements).

In November, chairman Dr John Prendergast will deliver the opening research and development address at the World Antimicrobial Resistance Congress, to be held in Washington on November 7.

Naturally, the jamboree features the who's who of the anti-infectives space.

"They are looking for what's next," Mr Graham says. "There hasn't been a new class of antibiotic for over 30 years and the drug maker's pipelines are not providing the innovation the space needs."

The reason for this is that antibiotics are cheap and generic and not worth the bother, although amoxicillin (brand name Amoxin) is still a $US10 billion a year global drug.

Doing a ‘recce’ on Recce

Recce was co-invented by the company’s founders, Dr Graham Melrose and Michele Dilizia, a medical scientist, former journalist - and Dr Melrose’s daughter.

Recce was incorporated in 2007 and listed in January 2016, having raised $5 million by issuing 25 million shares at 20 cents apiece.

Dr Melrose was executive director and chief research officer at Johnson & Johnson’s Australian arm.

Dr Melrose also headed the listed Chemeq, a veterinary drug outfit that was a market darling before collapsing in 2007 after alleged breaches of continuous disclosure requirements. Dr Melrose had departed the company by then.

Chemeq was tackling E coli infections in pigs and chickens, albeit using completely different technology.

With a degree in entrepreneurship, Mr Graham invested in Recce in 2013 before joining the company in 2015. James Graham is Dr Graham Melrose’s grandson.

Last year, Recce changed its name from Recce to the more descriptive Recce Pharmaceuticals.

The lowdown on Recce-327

Recce-327 works on a unique mechanism of action involving hydrophonic interaction with the offending cells. The antibiotic travels through the blood and is attracted to a protein in the bacteria’s outer membrane. This weakens the cell wall, causing the germs to burst (cell lysis).

The binding properties of Recce-327 mean that it is more effective in tackling superbugs and it is effective on both Gram negative and Gram positive bacteria (the bugs fall into these two classes, as determined by the structure of the cell walls).

Recce-327 is classed as a qualified infectious disease product (QIDP) by the US Food and Drug Administration, under the US Generating Antibiotic Incentives (GAIN) Act.

This designation is for what the FDA believes to be “serious life-threatening infections caused by an antibacterial or antifungal resistant pathogen”.
The QIDP status provides for 10 years’ exclusivity post-approval and also fast-track approval of any developed drug.

Recce-327, by the way, is manufactured at Recce’s Macquarie Park facility in Sydney, using cheap and abundant raw materials. The ingredients? Bog-standard polyethylene glycol, acrolein (a derivative of the common gas propene) and water (a non-patented amalgam of hydrogen and oxygen molecules).

It works on mice (and rats, rabbits and dogs).

Recce's key selling point is that Recce-327 does not lose its efficacy after 25 or more doses. In comparison, with E coli infections the standard antibiotics can only be used twice before resistance sets in.

Recce so far has carried out more than 30 in-vitro and in-vivo studies on mice, rats, rabbits and dogs, with the data used to support the push for QIDP status.

The company is now girding for a phase I study on healthy individuals, structured in the typical way of single and ascending doses, with Sydney's Royal North Shore Hospital spinal injury physician Dr David Bowers heading the clinical advisory committee.

In February, Recce submitted expanded preclinical data to the FDA, in view of gaining assent for a phase I human trial. Structured as a single ascending and multiple ascending dosing regime, the mooted trial will target enrolment of 44 healthy adult patients.

The trial will be randomized, double blinded and placebo-controlled. And because it's easy to tell whether the drug works or not, data should be available within months of starting the study.

In pre-clinical work, a curative trial of 30 mice infected with methicillin-resistant Staphylococcus aureus (MRSA) showed all 10 in the Recce-327 cohort survived, and nine in the current-use MRSA antibiotic (oxacillin) survived. Of the 10 not treated, four hardy critters survived.

A preventative study showed that in all treated rodents, the bugs cleared naturally from the blood after 12 hours. With the untreated cohort, the bacteria rapidly colonized in the kidneys, which "commonly results in catastrophic organ failure".

While sepsis is top of Recce's germ-busting agenda, the company is also eyeing the production animal market (E coli), antiseptics for hospitals, households and travellers and preservatives (cosmetics, toiletries and pharmaceuticals).

In a win for promiscuous rodents, early mice trials suggested the compound was effective against gonorrhoea (as well as tuberculosis).

"We have a lot of opportunities to broaden our product range," Mr Graham says.

Finances and performance

Before this week's capital raising Recce had been living a hand-to-mouth existence, as highlighted by the "material uncertainty" statements in the accounts.

As of June 30, the company had cash of $400,000, having derived no revenue in the 2018-'19 year and incurred a $1.67 million loss.

Recce has used various mechanisms to keep the cash trickling in, including third-party arrangements to release expected Federal Research and Development Tax Incentive payments for working capital.

In February the company raised $1.8 million in a placement at 14 cents a share to its supportive chums. It then raised $350,000 from local investors, repayable within six weeks or a capital raising “whatever is earliest”.

This week’s raising was struck at 26 cents a share, a 17.5 per cent discount to the prevailing price ahead of a trading halt on October 7.

Happy days! Mind you, Mr Graham sees joy in penury because the tight funding position has instilled management with a disciplined approach to spending.

“Some people would say ‘you poor thing’ but I’m quite proud of living on an oily rag.”

Valuation wise, Recce has graduated from poverty corner: its shares climbed from a 12-month low of 14 cents in late February to a peak of 38 cents on September 23. The stock hit a record 46 cents in January 2016.

Dr Boreham’s diagnosis:

It’s still early days for Recce, but the company is tackling an urgent medical problem and has posted encouraging results to date.

While investors are latching on to the story like Recce-327 to a recalcitrant bug, global deals suggest that Recce could - or should - be worth more than its current sub $40 million valuation.

This year French group Deinove entered a licencing deal with Britain’s Redx Pharma, which is all about whomping gram-negative bacteria.

Merck did likewise with the private Prokaryotics, which specializes in bacterial cell envelope enzymes.

In October 2017, Roche paid a heady $US387 million for Warp Drive Bio, a device company centred on detecting natural antibiotics.

Having got some much-needed dough through the door, Recce is one step closer to becoming the Mortein of the superbug world.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He is bugged by many things, but thankfully not sepsis, golden staph or E coli.