



# 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:** 76.5 cents; **Shares on issue:** 177,646,910; **Market cap:** \$135.9 million

**Chief executive officer:** James Graham

**Board\*\*:** Dr John Prendergast (chair), Michele Dilizia, James Graham, Dr Justin Ward, Dr Alan Dunton

\*\* Founder Dr Graham Melrose stepped down from the board in July 2020

**Financials (March 2022 quarter)\*:** revenue nil, operating cash burn \$117,958, cash of \$15.9m, quarters of available funding 135

\* The company received a \$3.08 million Federal Research and Development Tax Incentive during the period

**Major identifiable holders:** Dr Graham and Olga Melrose 21.6%, James Graham 3.4%, Michele Dilizia 1.9%, LDU Pty Ltd 1.7%.

Recce chief James Graham can speak from the heart about the dangers of sepsis, a life-threatening inflammation that spreads through the body via the blood as a result of infection.

Why? He was lucky not to die from the bacterial condition that kills about 20 percent of its 50 million sufferers.

After being attacked by a dog and clearly with an infection, Mr Graham hightailed it to hospital where they drew blood for a series of tests to match the bacteria with available antibiotics.

“It’s clinical guesswork,” he says.

“They will go through a broad-spectrum cocktail of antibiotics, hoping that one works.

“Every hour they are left untreated, the patient’s chances of survival decrease by eight percent.”

As it happened, Mr Graham’s staph infection was “fairly friendly” and easily treated.

But being a man of bioscience, he took along Recce’s antibacterial drug candidate – Recce-327 (R327) - just in case.

Medical rules allow for experimental treatments when traditional first-line therapy has been exhausted and the patient is in imminent threat of expiring.

“I had an intravenous drip in one arm and a vial [of R327] in another,” he says. “It was the back-up which fortunately we didn’t have to use.”

## **Germ warfare**

An exponent of the broader problem of bacterial resistant to antibiotics, sepsis is caused by Staphylococcus aureus (Golden Staph) and Escherichia coli (E coli) but can also be caused by fungi and viruses.

Another sobering sepsis stat is that the condition is responsible for one in three hospital deaths - which merely confirms our suspicion that hospitals aren’t healthy places.

“We are the only new class of antibiotic for sepsis at a clinical stage in the world,” Mr Graham says, noting there hasn’t been a new class of antibiotic for more than 30 years – primarily because the current ones are generic and cheap.

He says because there’s no approved treatment, the clinical focus is on reducing inflammation (the result of the immune system hyper-reacting to the infection).

“Frankly, that’s like putting the fire out in the back garden when the house behind you is burning down,” Mr Graham says.

“You can have some benefit in reducing the inflammatory response, but if you are not tackling the underlying bacteria and infection spreading out of control, what’s the point?”

## **Recc-on it will work?**

Recce's phase I work centres on the synthetic broad-spectrum antibiotic candidate R327 and the variant for viral infections, R529.

Star Wars fans should not confuse these with R2D2.

The compound was discovered by Dr Graham Melrose, a biochemist who headed Johnson & Johnson's Australasian research arm for a decade.

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

Dr Melrose's grandson, Mr Graham said his grandfather was motivated by the sudden death (from sepsis) of a football mate when he was in year nine.

Not one for golf or carpentry, Dr Melrose's idea of a man cave was dabbling with test tubes in the garage and eventually the Eureka moment happened.

While the efforts were philanthropic at first, Dr Melrose and Mr Graham got together to commercialize the venture. Mr Graham has a degree in entrepreneurship.

"It was my pop and I coming together on a 'best endeavours' basis and we were the sole first investors. He is a real inspiration to us all," Mr Graham says of his grand-dad, now aged 89.

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

Recce was co-founded by Dr Melrose's daughter Michele Dilizia, a medical scientist, former journalist and the company's chief scientific officer.

While Recce is headquartered in Sydney, Mr Graham recently moved to the US - sunny Florida in fact - to keep tabs on the company's operations there.

"We love what we do at Recce. It's about good people and great science," Mr Graham says.

## **Thank heaven for R327**

Recce-327 works on a mechanism of action involving hydrophobic 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 R327 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).

R327 is classed as a qualified infectious disease product (QIDP) by the US Food and Drug Administration, which means the regulator believes it can tackle “serious life-threatening infections caused by an anti-bacterial or anti-fungal resistant pathogen”.

Interestingly, R327 is derived from common-as-muck ingredients polyethylene glycol, acrolein (a derivative of propene) and water (a.k.a. Adam’s Ale or the elixir of life).

“Uniquely, it’s a whole solution,” Mr Graham says. “There is no singular active pharmaceutical ingredient; each and every part of the monomers in the polymers are working in unison as the active ingredient.”

Meanwhile, R529 is ‘same but different’. The manufacturing technique is similar, but the molecular structure and manufacturing steps are different enough to enable the compound to be patented.

Both are made at the company’s Macquarie Park facility in north-western Sydney.

### **Did someone mention Covid?**

Given Recce’s anti-viral ambitions, it should surprise no one that the company has been dabbling in a treatment for the dreaded and persistent Sars-Cov-2 (the virus at the heart of Covid).

The plague unfolded shortly after Mr Graham was made CEO, which afforded him no period of grace before facing the usual lockdown operational dramas.

On the clinical side, the company noticed that the CSIRO and Doherty Institute were running a priority testing program of possible treatments, so the company entered what Mr Graham dubs this “school fete competition for little entrants to have a go”.

“We made it through stage one with great success - 99.99 percent efficacy - and that moved us to stage two of a three-stage program.”

The next stage in the highly bureaucratic process is a bit vague, in that the company is “awaiting a mutually agreed outcome as to what may or may not happen next”.

One possibility is an all-in-one viral and bacterial prophylactic for sufferers of ‘long’ Covid.

Whatever the case, it’s very much a side program for Recce.

“Covid in my opinion will be with us for the time in hand and we have unique properties other compounds don’t,” Mr Graham says. “We are not there to participate in a ‘me too’ movement, but our compound appears to have good safety and efficacy on the virus side.”

## **Safety first**

Recce has been doing a dose-escalation study to assess the safety of R327 in injected doses anywhere between 50 milligrams and 16,000 milligrams.

Enrolling 80 healthy volunteers, the study is being done locally but is also being shaped by feedback from the US Food and Drug Administration.

On Tuesday, the company reported the 10 male subjects in the 4,000 milligram cohort did not keel over, turn purple or froth at the mouth. In other words, the compound at that strength exhibited “good safety and tolerability”.

The final 16,000 milligram cohort is expected to be completed by June 30 (a.k.a. EOFY)

Mr Graham says while the study currently is indicated for sepsis, by phase II it could be expanded to other conditions such as kidney and urinary tract infections.

## **Wood-n’t it be good to tackle burns?**

Alongside the dose escalation study, Recce has launched a Perth-based side program to show the efficacy of R327 as a spray-on topical treatment for burns infections.

This one is being overseen by prominent burns surgeon and Australian of the Year Prof Fiona Wood.

“Clinicians have reported a visible reduction in infection within the first 24 hours and a complete clinical response in all patients treated to date,” Mr Graham says.

He says the data will trickle out and should assuage the doubts of sceptics who think that R327 is no more than glorified infused water.

“We have something that has good safety and tolerability and meeting an unmet medical need.”

## **Finances and performance**

As of the end of March 2022 Recce had a cash balance of \$15 million, which provides a comfortable funding runway of 135.88 quarters (to be exact) on current cash burn rates.

The company raised \$28.5 million in a placement in September 2020, at \$1.30 apiece.

In 2018, Recce took out a \$20 million at the market (ATM) facility via a local intermediary.

Popular in the US, ATMs are a flexible fundraising mechanism enabling companies to issue shares and raise capital at a time of their choosing, typically in smaller amounts.

Over the last 12 months Recce shares have gyrated between \$1.35 (January 20, 2022) and 56 cents (last Monday). They spurted a lusty six cents (16 percent) on Tuesday, presumably on the back of the safety dosing news

Since listing they have traded as high as \$1.64 (September 20, 2020) and as low as 15 cents (November 2016).

Recce shares have lost one third of their value over the last 12 months, but Mr Graham says that's not too bad relative to many of the company's peers.

### **Dr Boreham's diagnosis:**

Mr Graham admits the dose escalation results are firmly in the 'boring but important' category.

But the burns side program promises some short-term sizzle - if that's not an inappropriate metaphor - for impatient investors.

"We don't do research for research's sake," he says. "We are working to a commercial outcome and that is to move the compound through the regulatory process as quickly as possible."

While Mr Graham is ensconced in Florida - amid a growing cohort of biotechs because of the tax breaks and other government assistance - the company will continue to be Australian based and ASX-listed.

"We are true blue as they come and unapologetic about it," he says.

"I may have personally moved to the US but at no stage have we ever considered turning our back on Australian shareholders or reducing our commitment to and investment in Australian activities."

***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.***