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Biocurious: It's spring, when a young man's fancy lightly turns to ... clinical trial results

By TIM BOREHAM



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- Crucial late-stage trial results are pending from Recce, Paradigm and Actinogen Medical
- The results are likely to make or break the companies' fortunes
- Alzheimer's drug developer Actinogen mulls a potential 'plan B' depression trial

Spring has sprung and what's not to love? Swooping magpies, hayfever and torrential rain notwithstanding, of course.

As well as increasing the ardour of animal species across the board, the season of reproduction has piqued the passion of investors awaiting key late-stage clinical trial results.

Before the advent of summer, we should know the upshot of pivotal studies from [Paradigm Biopharmaceuticals \(ASX:PAR\)](#) (knee osteoarthritis), [Actinogen Medical \(ASX:ACW\)](#) (Alzheimer's disease) and [Recce Pharmaceuticals \(ASX:RCE\)](#) (synthetic antibiotics).

Biocurious is loath to indulge in hyperbole, but the results are likely to be 'do or die' for these companies.

Success is likely to result in a multifold valuation uplift.



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As recent failed late-stage results have shown, failure amounts to a shattering blow that can wipe out decades of hard work.

The sector needs a win or two ... but no pressure at all.

Paradigm tackles huge unmet need

Investors may only have to wait days for the interim analysis on Paradigm's phase III trial of its knee osteoarthritis (knee pain) candidate, injectable pentosan polysulphate sodium.

Friends can call this one Zilosul.

Millions of knee osteoarthritis sufferers globally are keenly awaiting the results of the study, PARA-OA-012.

Two weeks ago, a data safety monitoring board completed its planned safety review of around 80% of participants who had completed dosing.

The review recommended the trial continue without modification, as did similar reviews at the 20% and 50% mark.

The company confirmed a September timeline for the interim readout.

But the timing remained "subject to completion of the required data cleaning, biometrics and independent review processes."

Biocurious asked Paradigm investor relations director, former AFL player and Zilosul recipient Simon White for a further steer on timing, but he only had this to say:

"It will be before the first siren of the Carlton v Fremantle 2026 grand final."

You read that one here first!

The study enrolled 538 patients, who were randomised to receive either Zilosul or a placebo on a one-to-one basis, over a six-week treatment period.

The recruitment exceeded the targeted 466 patients. The study is being carried out across 57 sites, 41 of them in the US and 12 in Australia.

The primary endpoint is the change in pain intensity at day 112, as per weekly average measurements.

The interim analysis covers 50% of participants.

The idea of Zilosul is to reduce the inflammation involved in knee OA. Zilosul is also thought to prompt actual cartilage regeneration, which is a secondary endpoint.

Investors are clearly punting on a positive result: the shares have spiked almost 30% in the last week and 40% over the last month.

Recce versus superbug

Synthetic antibiotic developer Recce tentatively hopes for interim results from its pivotal Indonesian phase III trial by the end of October.

Neatly, this date is 12 months after the trial kicked off.

The study road tests the company's Recce 327 gel (R327G), for diabetic foot infections (DFIs).

The need is apparent, given Indonesia's high diabetes rate.

Around 20 million adult Indonesians have the condition – often undiagnosed – and one in three will develop diabetic leg ulcers.

Almost half of the hospitalised patients will require amputations.

The interim analysis applies to the first 155 patients, recruited across five sites.

Should the results stack up, Recce hopes the drug will be approved and commercialised in Indonesia next year.

Aussie trial, you beaut

In May this year Recce signed a non-binding term sheet with a “leading Middle Eastern pharma company” for a ten-year, exclusive multi-country licensing deal.

Meanwhile, Recce is carrying out an Australian-based phase III DFI trial. The study aims for Australian and US approval.

Last month an ethics committee approved a trial protocol amendment, which enables the addition of a randomised, active-controlled, non-inferiority study arm.

The 208 patients receive either R327G, or one of four physician-selected antibiotics for comparison.

“Patient dosing continues under the existing trial protocol, with recruitment and treatment ongoing ahead of implementation of this newly approved amendment,” Recce says.

CEO James Graham says the ethics approval means recruitment can be widened to moderate, below-the-knee cases with multiple ulcers.

This accounts for around about 80% of the market.

Previously, the trial could only enrol below-the-ankle, mild cases with single ulcers. This cohort accounts for around 30% of the market.

“The is based on FDA accepted guidance and dramatically increases recruitment, market opportunity etcetera,” Graham says.

The company plans an interim analysis at the 104-patient mark. This is likely to occur in late 2027 or early 2028.

“R327G has the potential to become the first standard of care used by physicians for the treatment of DFIs,” Graham says.

R327 is one of four synthetic antibiotics Recce is developing.

The aim, of course, is to address the global problem of antibiotic-resistant superbugs.

Actinogen eyes Alzheimer’s breakthrough

In its pursuit of a better treatment for Alzheimer’s disease, Actinogen is comforted by late January’s ‘futility’ interim analysis which showed that continuing the pivotal trial would be – well – far from pointless.

Dubbed Xanamia, the pivotal phase IIb/III trial road tests Xanamem (emestedastat).

Xanamem targets the suspected role of excess brain cortisol levels in triggering the disease. The notion of cortisol’s involvement in the disease has been around for decades, but no one has quite been able to prove it.

Xanamem targets 11beta-hydroxy-steroid dehydrogenase type 1 (11beta-HSD1).

That’s not a Holden Special Vehicle, but a cortisol-producing enzyme expressed in parts of the brain governing memory and mood.

In its full year results last Thursday, Actinogen confirmed the study remained on track for topline final results in November.

The company reports that 89% of participants (108) have moved on to an open-label extension study.

“The good news is that as people are on the drug for longer and we are not seeing any surprising safety concerns,” says Actinogen CEO Dr Steven Gourlay.

Should the study pass master, Actinogen has agreed with the FDA and the European regulator on a streamlined further placebo-controlled pivotal trial of Xanamem.

“I’m feeling quite good about our program,” Gourlay says.

“Our endpoints are clear and it is good high-quality drug development.”

He stresses the trial relies on clinical outcomes – read: patient improvement – rather than high falutin’ biomarker measures (our words).

Plan B from biotech space

In July the peer-reviewed British Journal of Psychiatry published a write-up of Actinogen’s separate phase II proof-of-concept study.

The trial measured the effect of Xanamem on patients with major depression and cognitive impairment.

In short, the journal opined the drug was “worthy of further investigation.”

Gourlay says an Alzheimer’s therapy is “far and away” more valuable than a depression treatment.

But the company is open to pursuing a trial of depression in Alzheimer’s patients.

“We are not saying we will or won’t do it,” he says.

“Maybe we can do a trial in older patients, perhaps with dementia or maybe not.

“If we could get that antidepressant activity as a feature for the drug into the prescribing information locally, that would be a really nice boost to the value of the molecule.”

He says the current interest in psychedelics highlights the need for new depression treatments beyond the current selective serotonin reuptake inhibitors (SSRIs, such as Prozac).

Gourlay dubs the chances of a complete Alzheimer’s flop as unlikely, “as we have so much data showing the activity of the drug in the brain”.

The company posted a full-year net loss of \$15.3m, having incurred \$19m of R&D costs. With \$16m in the bank, the company is well funded into 2027.

“If we found ourselves in a sticky situation, we have the time and the money and the right people to sort that out.”

Actinogen shares have blipped 48% year on year, but more recently shareholders have kept a lid on their excitement.

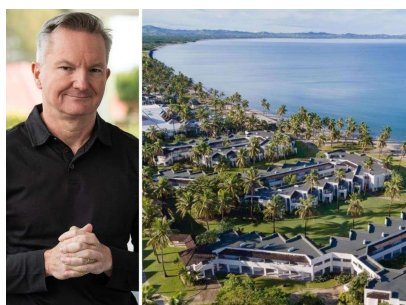
“Every CEO says we are hopelessly undervalued, but the net present value of a positive result is enormously higher than our current valuation,” Gourlay says.

A.k.a: 'we're dirt cheap, fill ya wellies'.

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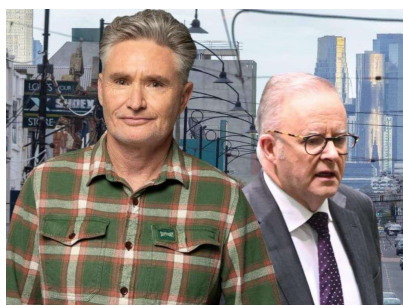
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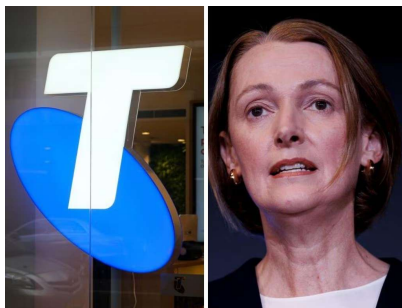
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