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Biocurious: It's spring, when a young



"Ooh that's nice but I would rather a statistically significant, randomised, double blinded trial readout." Pic: Getty Images

MoCruel 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.

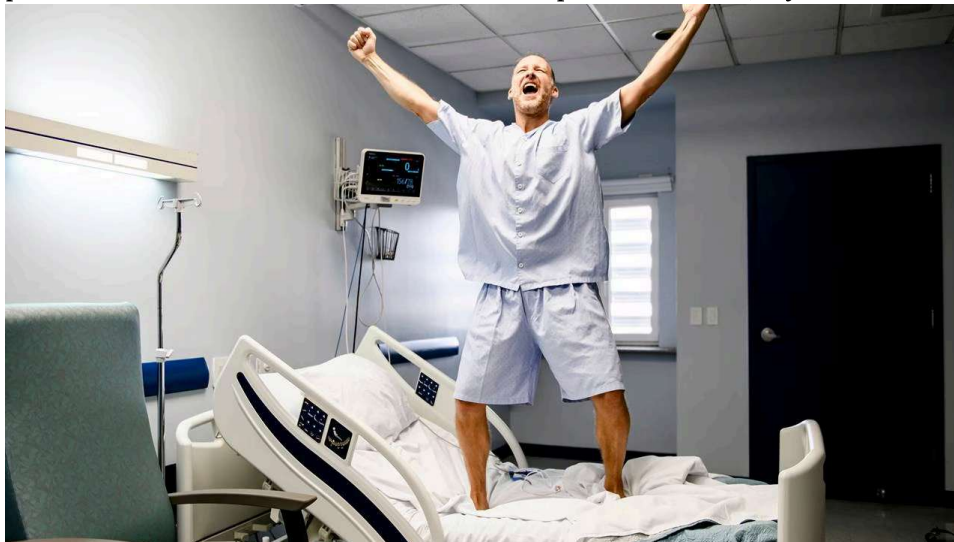


Stockhead

Paradigm tackles huge unmet need

Good morning! Here's everything you need to know before the ASX flings open its doors and begins trading today.

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



The company confirmed a September timeline for the interim readout.

Stockhead

ASX rises in volatile August

But the timing remained subject to completion of the required data cleaning, Biometrics and independent review processes. The S&P/ASX 300 rose 1.54% in August as health care dropped 19% to be top the performing sector for the month.

Biocurious asked Paradigm investor relations director, former AFL player and

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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. Blood spilt as chair, directors ousted at iconic Aussie company



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

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The idea of Zilosul is to reduce the inflammation involved in knee OA. Zilosul



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Recce versus superbug
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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.

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The study road tests the com ny’s Recce 327 gel (R327G), for diabetic foot infections (DFIs)

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The need is apparent, given Indonesia’s high diabetes rate.
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Around 20 million adult Indonesians have the condition – of how scammers now impersonate your bank – 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.
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Should the results stack up, Recce hopes the drug will be approved and new footage emerges as police criminalised in Indonesia
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Meanwhile, Recce is carrying out an Australian-based phase III DFI trial. The study aims for Australian rugby league talent facing assault, weapon charges

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The 208 patients receive e , or one of four physician-selected



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“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'.

And – no - we are not licensed financial advisers.

Originally published as [Biocurious: It’s spring, when a young man’s fancy lightly turns to ... clinical trial results](#)

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