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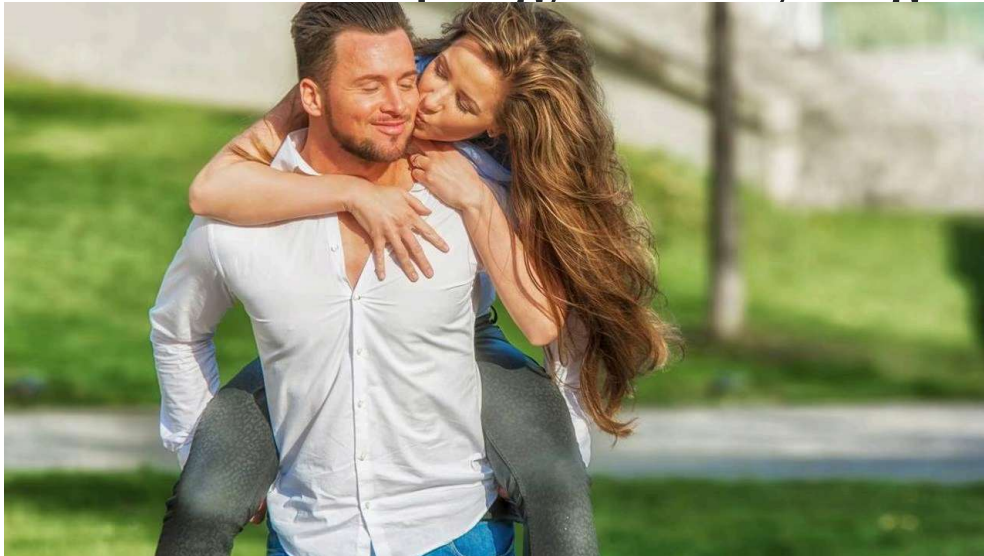
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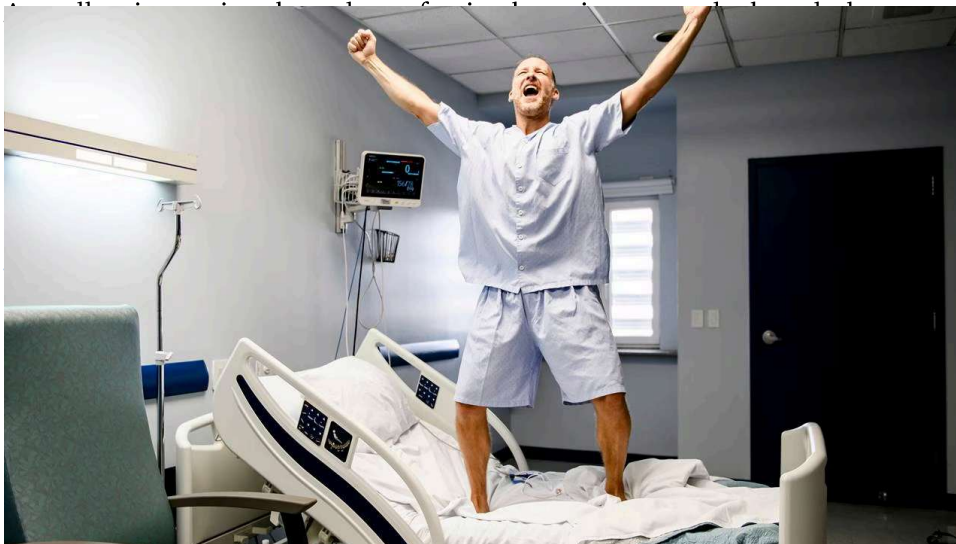
Biocurious: It's spring, when a young



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

- 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.



Stockhead
As recent failed late-stage results have shown, failure amounts to a shattering
ASX rises in volatile July with healthcare as best performer
The S&P/ASX 200 rose 1.54% in August as healthcare popped 19% to be top the performing
The sector needs a win or two ... but no pressure at all.



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Pilbara emerges as next copper frontier

The Pilbara has emerged as a copper growth story in Australian mining, with two mines heading towards construction. And there's more to come.

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ntatively hopes for interim results from

**Man sues Bunnings in
the end of October.
shock \$6m fight**

ce 32
Royals

The need is apparent, given Indonesia's high diabetes rate. **Formidables Andrew** accused of 'sex crimes in the US' have the condition – often with and one in three will develop diabetic leg ulcers.



Man with knife arrested

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Geelong theft spree



Almost half of the hospitalised patients will require amputations. **Bank's sad call: \$211k**

Bellarine battlers turn to

The interim analysis is applied

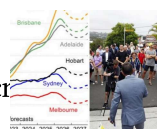
rebuild success



National

wiped from Aussies

at 155 patients, recruited across



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

Aussie trial, you beaut

Stockhead

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.

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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'.

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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