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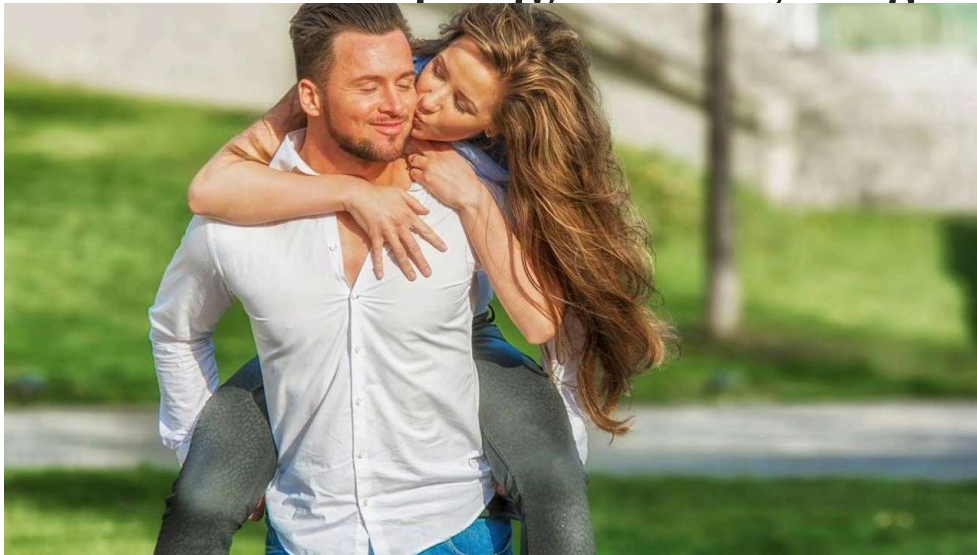
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Biocurious: It's spring, when a young



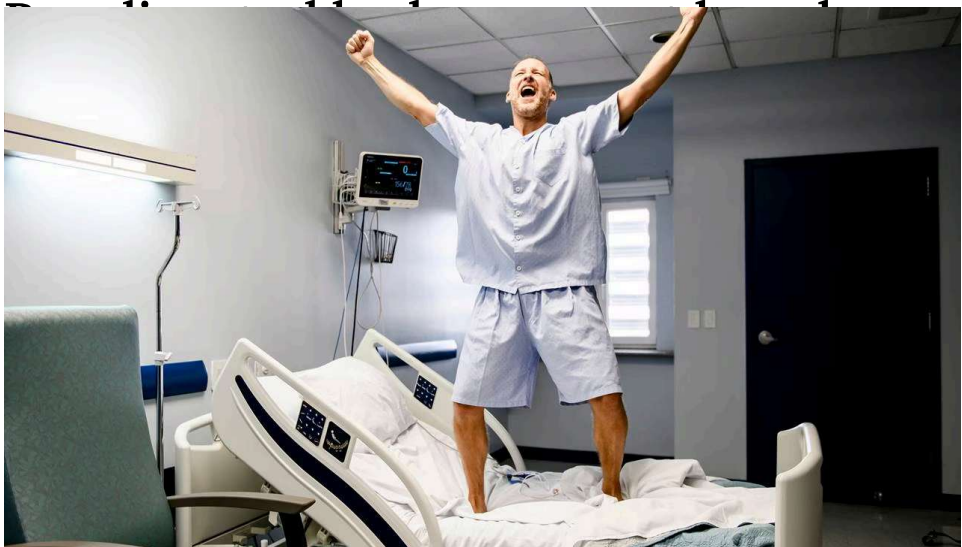
"Ooh that's nice but I would rather a statistically significant, randomised, double blinded trial readout." Pic: Getty Images

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- Moderna 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
Everything you need to know before the ASX opens
Good morning! Here's everything you need to know before the ASX flings open its doors and
The sector needs a win or two ... but no pressure at all.



Stockhead
The review recommended the trial continue without modification, as did
ASX rises in volatile August
similar reviews at the 20% and 50% mark.
The S&P/ASX 200 rose 1.54% in August as healthcare popped 19% to be top the performing
sector for the month.
The company confirmed a September timeline for the interim readout.

biometrics and independent review processes.”

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

**Blood spilt as chair
directors ousted at
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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.



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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.

weekly average measurements.

Good Morning George

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Recce versus superbug

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

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Neatly, this date is 12 month. After the trial kicked off.

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The study road tests the company's Recce 327 gel (R327/G), for diabetic foot infections (DFIs).

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

The simple fix for sweltering gyms

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



Almost half of the hospitalised patients will require amputations.

Trending now

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

North America

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In May this year Recce signed a "licensing deal" for a "Middle Eastern pharma company" for a "multi-licensing deal."

Tasmania



Royals

ending term sheet with a "le... interview claims



Meanwhile, Recce is carrying out a study aims for Australian



Commercial Real Estate

Australian-based phase III DFI trial. The oval.

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

Royals

The 208 patients receive either R327G, or one of four Andriav-
 The Fossil jumper is 'anti-itch' for some, but should the Devils wear it?
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 "Patient dosing continues under the existing trial protocol, with recruitment and treatment ongoing ahead of implementation of this newly approved amendment," Recce says.
 Mum speaks out after 12yo suicides following relentless bullying
 CEO James Graham says the ethics approval means recruitment 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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