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Gamble will come down to one final test



We've spent a lot of time talking about rocks lately.

Copper. Gold. Zinc. Lithium (don't worry, there'll be more).

But let's leave the drill rigs behind for a moment and head somewhere considerably more dangerous. The human brain.

Because while the mining sector has been giving us plenty to think about, there's another part of the market where a potentially enormous value-creating event is getting very close. And this one involves Alzheimer's disease.

The company is Actinogen Medical (ASX: ACW).

And, in November, we should find out whether its lead drug, Xanamem, can demonstrate if it works in Alzheimer's patients. Imagine that – a drug that has a positive impact on Alzheimer's ... potentially life-changing, right.

So right now, this is a crucial time to understand ACW and, more importantly, understand how to think about a biotech investment in general.

SWEET SKILLS

One of the reasons I like fundamental analysis is that the framework can travel.

Mining and biotech might look like completely different industries, but companies in both sectors move through stages. The same stages each time.

And, at each stage, the questions change.

could change the company's value? What happens if the next piece of evidence doesn't support the story?

That's exactly the mindset we use when analysing resource companies.

We don't just look at the project. We work out where the company actually sits in its journey, what has been demonstrated, what hasn't, and what needs to happen for the next stage of value creation to occur. Biotech is no different.

The terminology might change. The science is obviously very different. But the fundamental analysis process is surprisingly familiar.

SCIENCY BIT

ACW's thought is that excessive cortisol inside brain cells contributes to mental decline and other neurological (brain) problems. Its lead drug, Xanamem, is a pill designed to reduce cortisol production inside brain cells by inhibiting an enzyme called 11-HSD1. ACW is developing it primarily for Alzheimer's disease and Xanamem remains an investigational drug – not approved for use outside clinical trials.

THE CLINICAL TRIAL

ACW has studied Xanamem in more than 500 volunteers and patients across eight clinical trials, according to the company. But the big one is XanaMIA. This is a pivotal Phase 3 trial.

Participants receive either 10mg Xanamem or placebo for 36 weeks, with the trial designed to assess cognitive performance and clinical function.

The trial is fully enrolled and the company expects topline final results in November 2026.

This is where mining investors can use what they already know. A late-stage clinical trial result is not some distant exploration target. It's the equivalent of the drill results that could tell us whether all that work has produced an economically meaningful deposit.

RUN DMC

There has already been some potentially encouraging news around XanaMIA.

The independent Data Monitoring Committee (DMC) has made three positive recommendations for the trial to continue. But here's the critical distinction: That does not mean the drug has been shown to work. The company remains blinded to the data.

The DMC independently reviews the trial data and makes recommendations about whether the trial should continue. So I wouldn't read those three recommendations as some secret guarantee.

They aren't. Don't get me wrong – it's encouraging the DMC has recommended the trial continue, but it isn't a definite signal that the drug works.

to know four things.

1. Did the trial meet its primary endpoint? If it doesn't, things change very quickly.

2. How large was the effect? Statistical significance matters, but so does the size of the benefit. A result can be statistically significant without necessarily representing a dramatic improvement for patients.

3. Was the result clinically meaningful? The question isn't simply whether a statistical test has been passed. It's whether the treatment produces a meaningful benefit in people living with Alzheimer's.

4. What does it mean for the next stage? Does the data support another pivotal trial? Does it strengthen the regulatory pathway? Does it make Xanamem more interesting to potential partners?

That's the difference between reading a biotech announcement and actually analysing one.

had \$16.7 million. It said its cash run beyond the Xanamem results and into next year.

That's important. November marks the end of the story.

Interestingly, participants in the main trial chose to enter the open-label program, where Xanamem was given for safety and tolerance. But it's not clear if having a successful trial will help.

That's still very early data in November. It's not yet demonstrated.

HOW I SEE IT

This isn't me saying it will work. I've seen it from previous trials. It's definitely shown for this drug to work. But I don't know what happens in November.

Gold Coast **Bulletin**

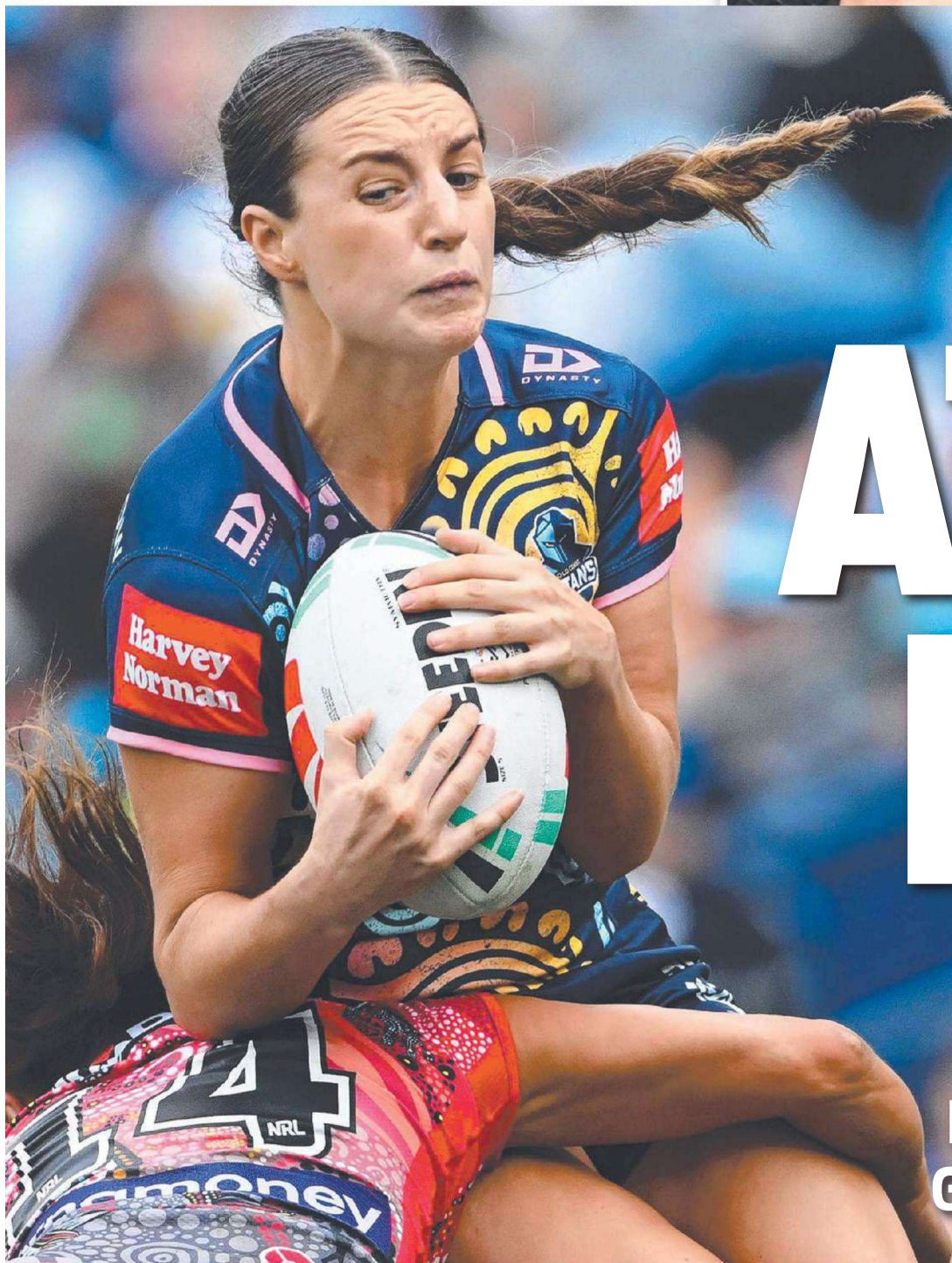
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GAME AWAY FR**

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