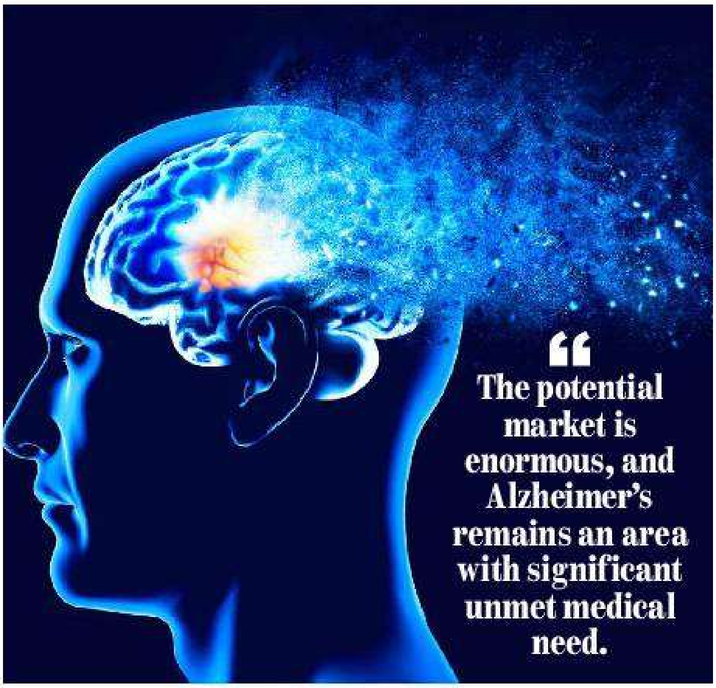
Craig  Dickson

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.

What has actually been proven? What remains uncertain? What is the catalyst that 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 2b/3 Alzheimer's trial involving 247 participants with mild-to-moderate Alzheimer's.

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.

TARGET NOVEMBER

When the results arrive, I want 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.

DOLLAR BUCKS

At the end of June, Actinogen had $16.7 million in cash and said its cash runway extended beyond the XanaMIA final results and into mid-2027.

That's important because November may not be the end of the story.

Interestingly, 88 per cent of participants completing the main trial chose to continue into the open-label extension program, where they receive Xanamem while longer-term safety and tolerability data is collected. But we shouldn't confuse having a pathway with having a successful drug.

That's still what the clinical data in November needs to demonstrate.

HOW I SEE IT

This isn't me saying Xanamem will work. I've read the data from previous trials, and it has definitely shown a good reason for this drug to be tested further. But I don't know what happens in November.

And neither does anyone else who isn't sitting on the final trial data. That's precisely what makes this interesting.

What I do know is that ACW is approaching one of those rare moments where a company can potentially move through a major stage transition very quickly.

From clinical hypothesis ... to clinical evidence. And if the data works, the conversation changes. The potential market is enormous, and Alzheimer's remains an area with significant unmet medical need. But the size of the opportunity doesn't make the drug work.

The data decides.

DISCLAIMER: This column is 100 per cent independent. Craig selects themes/companies based on educational and topical value. This article is not financial advice. Information and opinions provided in this column are general in nature and have been prepared for educational purposes only. Always seek personal financial advice tailored to your specific needs before making financial and investment decisions.

KEY INDICES AT 6PM

Index	Close	Change
All Ordinaries	8,951.00	31.90 ▲
ASX200	8,757.80	25.90 ▲
ASX50	8,529.50	17.60 ▲

Index	Last	Change
Dow Jones	52,048.83	366.19 ▲
Nasdaq	27,122.09	599.55 ▲
*Shangh Cmp	3,951.27	1.36 ▲
Nikkei 225	65,018.95	882.70 ▲
*Hang Seng	25,056.94	14.23 ▲
Euronext UK	2,121.28	4 ▼
CAC 40	8139.36	0.42 ▲

KEY RESOURCES

$US	Last	Change
Gold	4,323.68	20.04 ▼
Silver	65.55	0.87 ▼
Oil - Brent	97.14	0.90 ▲
Oil - WTI	93.01	0.64 ▲
Gas Oil	1,441.13	6.00 ▲
Nat Gas UK	184.49	3.08 ▲
Coal - Newc	144.00	1.00 ▲
Coffee	274.50	6.00 ▼
Cocoa	5,307.00	20.00 ▼
Sugar	18.28	0.10 ▼

KEY RATES

	Last	Change
Bitcoin	120,046.50	1,489.56 ▼
Cash rate	4.35	Steady
US 3yr	4.83	Steady
US 10yr	5.01	Steady

KEY CURRENCIES

$US	0.7112	▼ 0.08%
£UK	0.532	▼ 0.09%
€EURO	0. 62	▼ 0.04%
¥YEN	112.19	▲ 0.14%
$HK	5.58	▼ 0.10%
$NZ	1.24	▼ 0.55%

WINNERS ASX200

1	Sunrise Energy	12.73%
2	Electro Optics	8.22%
3	Telix Pharma	6.53%
4	Ingenia Comms	5.74%
5	Firefly Metals	5.65%
6	Silex Systems Ltd	5.42%
7	Bellevue Gold	4.83%
8	Ramelius Resources	4.73%
9	Lovisa Holdings	4.50%
10	Megaport Ltd	4.29%

LOSERS ASX200

1	Catalyst Metal	-14.37%
2	Resolute Mining	-4.43%
3	Origin Energy	-4.02%
4	4Dmedical Ltd	-2.92%
5	Droneshield Ltd	-2.64%
6	Woodside Energy	-2.37%
7	AGL Energy Ltd	-2.24%
8	Dyno Nobel Ltd	-2.23%
9	The A2 Milk Co	-1.94%
10	Karoon Energy	-0.03%

MOST ACTIVE VALUE

1	Macquarie Group	$241.54
2	NAB	$38.56
3	Telstra	$4.83
4	Santos	$8.65
5	BHP Group	$60.78

MOST ACTIVE VOLUME

1	PLS Group	20.27M
2	Cleanaway Waste	10.82M
3	Elolution Mining	5.70M
4	Qantas	3.19M
5	Fortscue Ltd	3.17M


m