Actinogen Medical

XanaMIA passes first safety milestone

Clinical study update

Healthcare

13 November 2025

Actinogen Medical reported that the independent Data Monitoring Committee (DMC) of the company's pivotal Phase IIb/III XanaMIA study in patients with mild-to-moderate Alzheimer's disease (AD) has met for the first time, and it has recommended that the study continues without modifications. The DMC has reviewed all available safety data to date from 153 XanaMIA study participants and has determined that no study modifications are indicated. This suggests that the drug continues to be well-tolerated and that its safety profile remains very favourable, which could be a key differentiator (provided it receives eventual regulatory approval), given well-recognised safety concerns with anti-amyloid treatments in AD. Actinogen plans to report a pre-planned interim efficacy (futility) analysis in early Q1 CY26 and final top-line study data in mid-Q4 CY26.

Year end	Revenue (AUDm)	PBT (AUDm)	EPS (AUc)	DPS (AUc)	P/E (x)	Yield (%)
6/24	9.9	(11.4)	(0.53)	0.00	N/A	N/A
6/25	5.5	(12.8)	(0.43)	0.00	N/A	N/A
6/26e	11.0	(17.2)	(0.53)	0.00	N/A	N/A
6/27e	22.0	(62.5)	(1.94)	0.00	N/A	N/A

Note: PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments. EPS is fully diluted.

The double-blinded XanaMIA Phase IIb/III study is designed to assess mild-to-moderate AD patients (with elevated blood levels of phosphorylated Tau-181, or pTau-181, at baseline), in c 240 patients across 35 sites in the US and Australia. Patients are randomised to take Xanamem 10mg or placebo once daily for 36 weeks. The primary endpoint is the drug's effect on AD progression using the FDA-recognised Clinical Dementia Rating – Sum of Boxes (CDR-SB), a comprehensive scale of functional capacities.

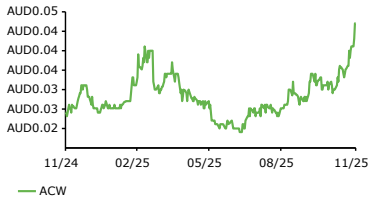
The DMC consists of independent clinical and statistical experts who are not connected to the day-to-day conduct or analysis of the trial, and are not affiliated with the company. Overall, the positive safety outcome from this first DMC meeting is not surprising, given that Xanamem has already shown a very robust safety profile in more than 400 patients across multiple other studies to date.

We note that Xanamem's efficacy was not assessed at the DMC meeting and the company reiterated that the DMC will meet again in late January 2026 to assess the safety and efficacy futility of the drug in the XanaMIA study. This analysis will use unblinded data for safety and efficacy futility analysis from all available participant visits, including many patients who will have already completed the entire 36-week treatment period of the study (under the trial's existing protocol).

This interim analysis is a key catalyst, as it will be the first major clinical readout for Xanamem in AD since the subset analysis from the earlier XanADu study. If this interim analysis supports the continuation of the trial, which we believe is likely given the XanADu subset data, investor and industry confidence in the programme may get a boost. The next critical milestone would then be the study's primary efficacy readout, expected in mid-Q4 CY26.

Price	**AUD0.047**
Market cap	**AUD149m**
Net cash at 22 October 2025	AUD10.5m
Shares in issue	3,178.5m
Free float	56.0%
Code	ACW
Primary exchange	ASX
Secondary exchange	N/A

Share price performance



Business description

Actinogen Medical is an ASX-listed Australian biotech developing its lead asset, Xanamem, a specific and selective 11beta-HSD1 inhibitor designed to reduce excess cortisol in the brain. It is being advanced to treat Alzheimer's disease (its lead indication) and major depressive disorder.

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