ASX ANNOUNCEMENT

Actinogen HY26 financial results: XanaMIA pivotal Alzheimer's trial progress and commercial readiness preparation

Sydney, 26 February 2026. Actinogen Medical ASX: ACW ("ACW" or "the Company") is pleased to release its interim financial results for the six months ended 31 December 2025.

Highlights

- Completed accelerated enrolment in the XanaMIA phase 2b/3 AD trial, randomizing the final (247th) participant in December 2025
- Received a positive interim safety and efficacy futility analysis recommendation from the trial's independent Data Monitoring Committee (DMC) on 30 January 2026 to continue the trial without amendment following a prior positive safety review in November 2025
- Open-label extension (OLE) phase of the XanaMIA trial to commence Q1 2026, allowing all participants access to active Xanamem® 10 mg once daily for a longer treatment period of up to 25 months
- Achieved a common understanding with the FDA on the pathway to marketing approval in AD, including agreement on the streamlined design of one further pivotal AD trial of Xanamem 10 mg vs. placebo commencing in 2027
- Successfully completed a pharmacokinetic trial confirming that the intended commercial Xanamem formulation achieves consistent and therapeutic blood concentrations under both fed and fasted conditions, supporting full dosing flexibility
- Completed commercial-grade manufacture of 10mg Xanamem tablets at Catalent (USA) for use in the OLE phase of the XanaMIA trial
- Continued commercial readiness activities, including refinement of communication materials for scientific, medical and business audiences, and establishment of a new AD clinical advisory board
- Continued strengthening of IP protection through active national phase patent filings
- Launched Actinogen's InvestorHub platform to facilitate direct investor engagement
- Received a total of $7.4 million R&D tax incentive cash rebate relating to expenditures in the 2025 financial year.[1]

Dr Steven Gourlay, the Company's CEO and MD, said:

"The first half of the 2026 financial year marked a period of significant progress for Actinogen as we completed enrolment in our pivotal XanaMIA Alzheimer's trial and prepared for the final phase of development and potential commercialization. With the positive recent interim analysis of safety and efficacy futility reinforcing confidence in the program, we are strongly positioned as we progress toward the topline final results for the full 247-participant dataset in November this year."

"Xanamem has the potential to be a transformative therapy for people living with Alzheimer's disease, offering a promising safe and effective oral therapy to slow or halt disease progression."

® Xanamem is a registered trademark of Actinogen Medical Limited

[1] Unless stated otherwise, all financial data is in Australian dollars

2026 Interim report

Shareholders are encouraged to review the Actinogen *Interim Report 2026* released today in digital format, which provides financial statements and an Operating and financial review for the six months ended 31 December 2025, including details supporting the highlights outlined in this announcement.

The Interim report is available on the Actinogen InvestorHub:
https://investors.actinogen.com.au/announcements

Statutory financial results

The statutory results for the first six months of the 2026 financial year reflect the Company's ongoing investment in developing and advancing its lead molecule Xanamem for the treatment of Alzheimer's disease and depression.

The Net loss after tax for the half year ended 31 December 2025 was $11,346,952 (HY ended 31/12/2024: loss of $8,168,979).

The major expenditure item for the half year was Research and Development costs of $8,902,759 (HY ended 31/12/2024: $4,582,920), primarily relating to clinical trials.

Financial position

At 31 December 2025, the Company had a Cash and cash equivalents balance of $6,531,460 (FY ended 30/6/2025: $16,504,240). Subsequent to the end of the half, the company announced a number of significant funding events including:

- Accessing a further $4.3m in non-dilutive loan funding secured against the R&D rebate accrued to 31/12/2025
- Receipt of a further $1.9m R&D rebate relating to R&D expenditures incurred during FY2025, bringing the total R&D rebate received for FY2025 to $7.4m
- A placement to raise $12m from existing and new institutional and sophisticated investors, including a commitment for $0.5m from CEO, Dr Steven Gourlay (subject to shareholder approval at a General Meeting to be held 18 March 2026)
- A Share Purchase Plan to raise up to $5m from existing shareholders, with the ability to take oversubscriptions.

Following these funding initiatives, the company's proforma cash balance as at 31 December 2025 was $29.7m (as announced 2 February 2026), providing sufficient liquidity to fund the company beyond the XanaMIA clinical trial topline final results anticipated for November 2026.

Outlook

The Company remains confident about its prospects in FY2026 and beyond, following a successful FY2025. Clinical momentum continues with the receipt of a positive interim safety and efficacy futility analysis recommendation from the DMC to continue the XanaMIA trial without amendment, alongside the earlier positive safety review in November 2025. These assessments support confidence in the underlying trial design and continuation of the trial toward topline final results in November 2026, following the last patient's final evaluation visit expected in September 2026.

The XanaMIA phase 2b/3 AD trial is planned to serve as one of two pivotal trials supporting the earliest possible marketing approvals for Xanamem in AD. Should the trial prove positive as expected, the company will also explore accelerated approval pathways with relevant regulators. In particular, we will discuss with the FDA its recently announced policy to approve drugs with a single pivotal trial provided there is adequate supporting evidence.

Actinogen is in an enviable position, with multiple independent trials providing clinical validation of Xanamem's brain cortisol control mechanism relevant to AD, depression and related neurological conditions:

- Positive results on depressive symptoms in a well-controlled, phase 2 trial
- Encouraging pilot data in AD patients with elevated pTau181 (Taylor et al 2024) suggesting the potential of Xanamem to stabilize AD
- High brain target enzyme binding in a human PET scan study (Villemagne et al 2024)
- A promising safety profile, with more than 500 individuals treated with active drug for up to 36 weeks and no reported serious adverse events related to Xanamem.

Upcoming catalysts include notification of a new peer-reviewed publication, academic presentations, EMA feedback on the AD program, clinical trial updates, and topline final results for the XanaMIA AD trial in November 2026.

The company continues to prioritize manufacturing, regulatory, clinical pharmacology and nonclinical planning and activities to enable rapid expansion should phase 2b/3 results be successful.

We firmly believe in the high quality of our late-stage clinical development program for oral Xanamem in AD. Our trials are science-driven, and we have safely treated more than 500 people with active Xanamem for up to 36 weeks. Xanamem has the potential to be a first-in-class, disease-course modifying drug for the treatment of AD with its novel cortisol-control mechanism. The program provides great hope to patients with AD and their families because there remains a significant unmet medical need for safer and more effective therapies.

Actinogen remains committed to proactive management across all aspects of the business to deliver the best outcomes for patients and shareholders, including optimizing our current clinical trials program, progressing regulatory planning for marketing approvals, advancing partnering initiatives and building optimal shareholder returns.

View this announcement on our InvestorHub: https://investors.actinogen.com.au/link/yMQ2by

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Dr Steven Gourlay
CEO & Managing Director
P: +61 2 8964 7401
E. steven.gourlay@actinogen.com.au

Investors

Michael Roberts
Investor Relations
M: +61 423 866 231
E. michael.roberts@actinogen.com.au

Media

George Hazim
Media & Public Affairs Australia
M: +61 417 516 262
E: georgehazim@mediaaffairs.com.au

Announcement authorised by the Board of Actinogen Medical Limited

About Actinogen Medical

Actinogen Medical (ACW) is an ASX-listed, biotechnology company developing a novel therapy for neurological and neuropsychiatric diseases associated with dysregulated brain cortisol. There is a strong association between cortisol and detrimental changes in the brain, affecting cognitive function, harm to brain cells and long-term cognitive health.

Cognitive function means how a person understands, remembers and thinks clearly. Cognitive functions include memory, attention, reasoning, awareness and decision-making.

Actinogen is currently developing its lead compound, Xanamem, as a promising new therapy for Alzheimer's Disease. It has also conducted a phase 2 trial in patients with cognitive impairment and depression and may study Fragile X Syndrome and other neurological and psychiatric diseases in the future. Reducing cortisol inside brain cells could have a positive

impact in these and many other diseases. The cognitive dysfunction, behavioural abnormalities, and neuropsychological burden associated with these conditions is debilitating for patients, and there is a substantial unmet medical need for new and improved treatments.

Clinical Trials

The XanaMIA Phase 2b/3 Alzheimer's disease trial is a double-blind, 36-week treatment, placebo-controlled, parallel group design trial in 247 patients with mild to moderate AD and progressive disease, determined by clinical criteria and confirmed by an elevated level of the pTau181 protein biomarker in blood. Patients receive Xanamem 10 mg or placebo, once daily, and its ability to slow progression of Alzheimer's disease is assessed with a variety of endpoints. The primary endpoint of the trial is the internationally-recognized CDR-SB (Clinical Dementia Rating scale – Sum of Boxes). The trial is being conducted in Australia and the US and is now closed to participant recruitment. It has passed an independent Data Monitoring Committee safety and efficacy futility review and final topline results are expected in November 2026.

The XanaMIA-OLE Alzheimer's disease open-label extension is an open-label phase of up to 25 months treatment where all participants will receive active Xanamem 10 mg once daily. The trial will evaluate safety and a limited number of efficacy endpoints such as the CDR-SB. The trial will commence in Q1 2026 and be open to all former and current participants in the XanaMIA Phase 2b/3 trial.

The XanaCIDD Phase 2a depression trial was a double-blind, six-week proof-of-concept, placebo-controlled, parallel group design trial in 167 patients with moderate, treatment-resistant depression and a degree of baseline cognitive impairment. Participants were evenly randomized to receive Xanamem 10 mg once daily or placebo, in most cases in addition to their existing antidepressant therapy, and effects on cognition and depression were assessed. Trial results were reported in August 2024 and showed clinically and statistically significant benefits on depression symptoms with positive effects on the MADRS scale (a validated scale of depression symptom measurement) and the PGI-S (a valid patient reported assessment of depression severity). Cognition improved markedly and to a similar extent in both Xanamem and placebo groups.

About Xanamem (emestedastat)

Xanamem's novel mechanism is to control elevated levels of cortisol (aka the "stress hormone") in the brain through the inhibition of the cortisol synthesis enzyme, 11β-HSD1, without affecting production of cortisol by the adrenal glands which is essential for the body's normal functioning. Xanamem is a first-in-class, once-a-day pill designed to deliver high levels of cortisol control in key areas of the brain related to Alzheimer's and other diseases such as the hippocampus and frontal cortex. To view Xanamem's two-minute Mechanism of Action animation, click here.

Chronically elevated cortisol is associated with progression in Alzheimer's Disease and excess cortisol is known to be toxic to brain cells. Cortisol itself is also associated with depressive symptoms and when targeted via other mechanisms has shown some promise in prior clinical trials. The recent XanaCIDD trial demonstrated clinically and sometimes statistically significant benefits on depressive symptoms, further validating the cortisol control mechanism for the Xanamem 10 mg oral daily dose.

The Company has studied 11β-HSD1 inhibition by Xanamem in more than 500 volunteers and patients in eight clinical trials. Xanamem has a promising safety profile and has demonstrated clinical activity in patients with depression, patients with biomarker-positive Alzheimer's disease and cognitively normal volunteers. High levels of target engagement in the brain with doses as low as 5 mg daily have been demonstrated in a human PET imaging study.

Xanamem is an investigational product and is not approved for use outside of a clinical trial by the FDA or by any global regulatory authority. Xanamem® is a trademark of Actinogen Medical.

Disclaimer

This announcement and attachments may contain certain "forward-looking statements" that are not historical facts; are based on subjective estimates, assumptions and qualifications; and relate to circumstances and events that have not taken place and may not take place. Such forward looking statements should be considered "at-risk statements" - not to be relied upon as they are subject to known and unknown risks, uncertainties and other factors (such as significant business, economic and competitive uncertainties / contingencies and regulatory and clinical development risks, future outcomes and uncertainties) that may lead to actual results being materially different from any forward looking statement or the performance expressed or implied by such forward looking statements. You are cautioned not to place undue reliance on these forward-looking statements that speak only as of the date hereof. Actinogen Medical does not undertake any obligation to revise such statements to reflect events or any change in circumstances arising after the date hereof, or to

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ACTINOGEN MEDICAL ENCOURAGES ALL CURRENT INVESTORS TO GO PAPERLESS BY REGISTERING THEIR DETAILS WITH THE DESIGNATED REGISTRY SERVICE PROVIDER, AUTOMIC GROUP.