ASX ANNOUNCEMENT

Actinogen FY2026 results – pivotal Alzheimer's trial results imminent

Sydney, 27 August 2026. Actinogen Medical ASX: ACW ("ACW" or "the Company") is pleased to release its financial results and annual report for the year ended 30 June 2026.

Highlights – Imminent pivotal trial results in Alzheimer's disease:

- Pivotal Alzheimer's disease trial remains on track for topline, final results in November this year following three positive Independent Data Monitoring Committee (DMC) recommendations, including a confidential "non-futility" review of unblinded efficacy data in January
- Open-label extension phase of the XanaMIA trial commenced March 2026, with 89% of participants moving directly to the OLE at the end of the main trial, and a total of 108 now on treatment
- Achieved common understandings with the US FDA and the European Medicines Agency (EMA) on the pathways to marketing approvals in Alzheimer's disease (AD), including agreement on the streamlined design of one further pivotal AD trial of Xanamem 10 mg versus placebo commencing in 2027
- Peer-reviewed depression trial manuscript detailing positive anti-depressant activity published in *British Journal of Psychiatry*
- June-end cash balance of $16.7 million provides cash runway beyond Alzheimer's trial final results to mid-2027
- Completed manufacture of an additional batch of 10mg Xanamem tablets at Catalent (USA) for use in the OLE phase of the XanaMIA trial
- Strengthened IP protection through active national phase patent filings with the first national acceptances received for new patents covering Xanamem treatment of cognitive decline in healthy elderly people and key manufacturing steps
- Enhanced our relationships with key stakeholders by focusing on the importance and uniqueness of Xanamem's brain cortisol control mechanism in AD and our impending pivotal trial data
- Received $7.3 million research and development tax incentive (RDTI) rebate from the Australian Tax Office relating to the 2025 financial year.

Actinogen CEO, Dr Steven Gourlay said:

"FY2026 has been a defining year for Actinogen. We achieved every major objective we set ourselves, including timely enrolment of the pivotal XanaMIA Alzheimer's disease trial and its successful interim efficacy futility and safety review, securing alignment with both the FDA and EMA on relatively streamlined pathways to marketing approvals, and establishing a cash runway beyond mid-2027."

"Xanamem is a leading and unique late-stage oral therapy in clinical development for Alzheimer's disease with the potential to become a transformational treatment option for patients and their families living with this devastating condition. Our key focus is to deliver high-quality pivotal trial results in November while at the same time planning the future activities needed to get Xanamem approved as soon as possible by regulators."

FY2026 Annual Report

Shareholders are encouraged to review the Company's 2026 digital annual report released separately to the ASX today which provides full financial statements and a comprehensive analysis of activities and

achievements for the year ended 30 June 2026, including details supporting the highlights outlined in this announcement.

The digital annual report is also available in the Recent Annual Reports section under the Our Company tab of the Company's website www.actinogen.com.au.

Statutory financial result

The statutory result for the 2026 financial year reflects the Company's ongoing investment in developing and advancing its lead molecule Xanamem for the treatment of Alzheimer's disease.

The Net loss after tax for the twelve months ended 30 June 2026 was $15,379,848 (FY2025: loss of $14,732,263).

The major expenditure item for the year was Research and development costs of $19,027,365 (FY2025: $12,296,568), primarily relating to clinical trials.

Financial position

At 30 June 2026, the Company had a Cash and cash equivalents balance of $16,734,937 (30 June 2025: $16,504,230). The Company's FY2026 R&D tax rebate accrual is $10,817,407, which is expected to be received in Q2 FY2027.

Outlook

The need for improved Alzheimer's disease treatments is clear and urgent. Current therapies remain limited in their effectiveness and safety. The Company believes that Xanamem's unique mechanism of action, oral administration and promising safety profile positions it as a potentially important breakthrough therapy for Alzheimer's disease, depression and other neurodegenerative and psychiatric diseases.

As we look ahead to FY2027, our three major priorities are clear:

1. Successfully complete the XanaMIA trial and deliver a high-quality final dataset in November
2. Continue preparations for the next phase of regulatory and clinical development
3. Actively pursue strategic partnership opportunities that maximize the value of Xanamem globally.

Actinogen remains committed to proactive management across all aspects of the business to deliver the best outcomes for patients and value for shareholders.

View this announcement on our InvestorHub: https://investors.actinogen.com.au/link/yan9Ke

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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 evaluates safety and a limited number of efficacy endpoints such as the CDR-SB. The trial commenced in March 2026 and is 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. The peer-reviewed publication relating to this trial can be accessed for free via this link: https://tinyurl.com/ckm63z63.

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 reflect the occurrence of or non-occurrence of any future events. Past performance is not a reliable indicator of future performance. Actinogen Medical does not make any guarantee, representation or warranty as to the likelihood of achievement or reasonableness of any forward-looking statements and there can be no assurance or guarantee that any forward-looking statements will be realised.

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