ASX ANNOUNCEMENT

Actinogen FY2025 financial results – accelerating toward pivotal trial results in Alzheimer's disease

Sydney, 25 August 2025. Actinogen Medical ASX: ACW ("ACW" or "the Company") is pleased to release its financial results and annual report for the year ended 30 June 2025.

Highlights – Highly productive year of value-add activities:

Advanced two major clinical trial programs:

- XanaMIA phase 2b/3 Alzheimer's disease (AD) clinical trial passed 100th participant milestone. Interim analysis scheduled for January 2026 and final results expected Q4 2026
- Completed XanaCIDD phase 2a major depressive disorder (MDD) trial – using the data to support development in Alzheimer's disease pending independent funding for additional MDD trials.

World Health Organization granted new and unique International Nonproprietary Name (INN) 'emestedastat' to Xanamem®

Successfully conducted a Type C regulatory meeting on MDD with the US Food & Drug Administration (FDA)

Conducted commercial readiness planning in all other major aspects of the business including appointing an experienced Chief Commercial Officer (CCO) to manage commercialization activities, conducting partnering meetings & discussions, protecting intellectual property (IP), conducting regulatory meetings, initiating the clinical pharmacokinetic trial and other ancillary studies

Published an academic manuscript in peer-reviewed journal, Clinical Pharmacology in Drug Development

Completed production of a 15kg scale-up batch of drug substance from contract manufacturer, Asymchem, which will be manufactured in the US into Xanamem tablets for use in the current and future trials, and confirm readiness for future commercial quantity production

Completed an $11.1m capital-raising, received a $9.0 million Research & Development (R&D) tax incentive rebate and established a $13.8m non-dilutive R&D tax incentive funding facility. Funding secured to mid-late CY2026

Delivered another in the series of 'plain English' Clinical Trials Science Forum (CTSF) neuroscience webinars with the subject title *The critical importance of preparing for commercialization*

CEO, CMO and CCO presented at numerous significant international conferences and conducted meetings at industry gatherings to continue evaluating potential value-add regional and global business development opportunities.

® Xanamem is a registered trademark of Actinogen Medical Limited

Actinogen CEO, Dr Steven Gourlay said:

"FY25 was a year of many accomplishments and a testament to the skill and dedication of our team and many investigative Alzheimer's disease trial sites. We now have a clear timeline for the planned interim analysis for the XanaMIA trial in January 2026 with final results expected late in the year. As these key clinical milestones approach the team is busy optimizing the many aspects of Xanamem's development program designed to prepare the Company for partnering and eventual marketing approvals."

FY2025 Annual Report

Shareholders are encouraged to review the Company's 2025 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 2025, 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 https://actinogen.com.au/.

Statutory financial result

The statutory result for the 2025 financial year reflects 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 twelve months ended 30 June 2025 was $14,732,263 (FY2024: loss of $13,044,282).

The major expenditure item for the year was Research and Development costs of $12,296,568 (FY2024: $15,535,482), primarily relating to clinical trials.

Financial position

At 30 June 2025, the Company had a Cash and cash equivalents balance of $16,504,230 (30 June 2024: $9,450,735). The Company's FY2025 R&D tax rebate accrual is $5,489,600, which is expected to be received in Q2 FY2026. There is a further portion of research and development expenditure for which eligibility remains subject to the ATO's review and approval of an Advanced Overseas Finding application submitted by the Company. Should this application be approved, there will be a further $1,874,143 of RDTI received by the Company, likely during the quarter ending 31 December 2025.

Outlook

The Company remains confident about its prospects in FY2026 and beyond as we look to build on a successful FY2025. Actinogen continues its transformational clinical development of Xanamem as it surpasses halfway in recruitment for the XanaMIA phase 2b/3 AD trial, with final results for 220 participants anticipated in late 2026.

XanaMIA is planned as one of two pivotal trials to support the earliest possible marketing approvals for Xanamem in AD. Should the trial prove positive as expected, pathways to accelerated approvals will also be explored with regulators.

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 diseases:

- Positive results on depressive symptoms in a well-controlled, phase 2 trial
- Encouraging pilot data (Taylor et al 2024) suggesting stabilization of mild AD
- High brain target enzyme binding in a human PET scan study (Villemagne et al 2024)

- No serious adverse events related to Xanamem and promising safety profile in more than 400 people treated with active drug for up to 36 weeks.

Upcoming news events include notification of a new peer-reviewed publication, academic presentations, results of FDA and EMA interactions on AD, clinical trial updates, interim data from the XanaMIA phase 2b/3 AD trial in January 2026, and final results in late 2026.

We continue to prioritize additional manufacturing, regulatory, clinical pharmacology and nonclinical planning and activities to enable rapid expansion on successful phase 2b/3 results.

The Company remains committed to proactive management of all aspects of its business to ensure the best possible outcomes for shareholders. This includes optimizing our current clinical trials program and forward planning for marketing approvals while balancing partnering efforts and building optimal shareholder returns.

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Announcement authorised by the Board of Actinogen Medical

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 and Depression and hopes to 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 220 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. Initial results from an interim analysis triggered by the 100th participant reaching 24 weeks of treatment are anticipated in January 2026 and final results Q4 2026.

The XanaMIA-DUR Alzheimer's disease open-label extension trial is an open-label trial of up to 24 months 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 of action is to control the level of cortisol in the brain through the inhibition of the cortisol synthesis enzyme, 11β-HSD1, without affecting production of cortisol by the adrenal glands. Xanamem is a first-in-class, once-a-day pill designed to deliver high levels of cortisol control in the brain. To view Xanamem's two-minute Mechanism of Action video, 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.

The Company has studied 11β-HSD1 inhibition by Xanamem in approximately 400 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.