



ASX ANNOUNCEMENT

Actinogen December 2025 quarterly activity report and Appendix 4C

Sydney, 30 January 2026. Actinogen Medical ASX: ACW (“ACW” or “the Company”) is pleased to announce the release of its quarterly activity report and Appendix 4C for the three-month period ended 31 December 2025.

Highlights and key events:

Pivotal XanaMIA phase 2b/3 Alzheimer’s disease (AD) trial – final, 247th participant randomized in December 2025 and positive Interim Analysis outcome January 2026. Topline final results in November 2026

- The pivotal XanaMIA phase 2b/3 AD trial enrolled 247 participants (original target 220) with elevated levels of the blood biomarker pTau181, designed to identify participants with biomarker-positive AD whose disease is likely to progress during the 36-week treatment period of the trial, and therefore augment the ability to detect a Xanamem[®] (emestedastat) treatment benefit
- The XanaMIA AD trial’s independent Data Monitoring Committee (DMC)¹ has recommended that the trial continue without amendment after its interim analysis. In doing so, the DMC determined that the unblinded safety and efficacy data it reviewed support continuing the trial to its completion later in the year
- Previously, the Company announced in November a positive recommendation from the first meeting of the independent DMC overseeing the trial which reviewed all available safety data from 153 XanaMIA trial participants to that date and concluded that the trial should continue without amendment²
- Trial topline final results are expected in November 2026.

The XanaMIA AD trial open label extension (OLE) phase to commence this quarter (Q1 2026)

- An open-label phase of up to 25 months treatment where all participants will receive active Xanamem 10 mg once daily and no placebo control group is used
- Open to all former and current participants in the XanaMIA phase 2b/3 AD trial
- Provides longer term safety data for at least 12 months and observational data on key efficacy endpoints such as the CDR-SB, cognition and activities of daily living.

Other key activities

The Company continues to progress an important range of initiatives appropriate to late-stage clinical development. These include:

- **Manufacturing** – completed manufacturing of drug product (10mg Xanamem tablets) at Catalent in the US intended for the OLE phase of the XanaMIA AD trial

[®] Xanamem is a registered trademark of Actinogen Medical Limited

¹ The DMC comprises independent clinical and statistical experts who are not connected to the day-to-day conduct or analysis of the trial

² Efficacy of Xanamem was not evaluated at the first meeting

- **Commercial planning** – the Company’s Chief Commercial Officer, Mr. Andy Udell, continues to refine the Company’s communication materials to support a stronger presence at key AD scientific and business meetings, and has further advanced commercial communication materials including the findings from the Company’s independent market research. During the quarter, the Company convened its first Alzheimer’s Disease Clinical Advisory Committee, expanding engagement with key thought leaders through a globally representative group of nine experts to inform ongoing clinical and commercial planning
- **Partnering** – dialogue continues with multiple parties spanning potential regional and/or global partnership arrangements, with an emphasis on those regional organizations that are interested in a breakthrough AD product. Several of those parties are active in the Company’s dataroom. With the positive formal Interim Analysis outcome and rapidly approaching final results, increased engagement with global and regional partners is anticipated
- **Intellectual property (IP) protection from future generic competition** – the Company continues to prosecute national phase patent applications for multiple new patents, designed to strengthen and extend IP protection for Xanamem beyond that afforded by earlier patents and the data exclusivity laws that apply to novel medicines
- **Other ancillary studies** – preparations continue for an open-label extension (OLE) trial to allow all participants in the XanaMIA trial access to longer-term active Xanamem therapy. This trial is due to commence in the current quarter (Q1) 2026.

Presented at international and Australian conferences and conducted investment and partnering meetings:

- On 21 October 2025, CEO Dr Steven Gourlay presented a short review to analysts and investors at the Canaccord Drug & Device Conference and conducted a number of small group meetings
- During the week commencing 3 November 2025, Dr Gourlay and Chief Commercial Officer, Mr Andy Udell attended Europe’s largest partnering event, the BIO³ Europe partnering conference in Vienna Austria. During the event, Dr Gourlay and Mr Udell engaged with international investors and potential biopharma partners throughout the conference to discuss Actinogen’s late-stage AD clinical trial program and the enormous market potential for Xanamem
- On 19 November 2025, Dr Gourlay and Chief Financial Officer, Mr Will Souter presented at the Bell Potter Healthcare conference. The Company’s presentation was titled Oral Xanamem®: Controlling brain cortisol to slow progression in Alzheimer’s disease and treat depression
- Earlier in January, Dr Steven Gourlay was joined by Andy Udell, Will Souter and Chief Medical Officer, Dr Dana Hilt at the Sachs Associates 9th Annual Neuroscience Innovation Forum in San Francisco. While in San Francisco, the team also participated in a significant number of partnering, analyst and investor meetings associated with the 44th Annual J.P. Morgan Healthcare Conference, known as JPM Week.

Actinogen CEO and MD, Dr Steven Gourlay said:

“The December quarter of 2025 was significant for the achievement of early closing of recruitment in our pivotal XanaMIA Alzheimer’s trial due to accelerated participant enrolment during the second half of the year, and higher enrolment than originally anticipated.”

“The new year heralds further key late-stage milestones for Actinogen in our differentiated Alzheimer’s program. These include the announcement today of the positive outcome of the interim analysis for the XanaMIA trial conducted by an independent Data Monitoring Committee; the expected receipt of scientific

³ The Biotechnology Innovation Organization (BIO) is the world’s largest advocacy association for biotechnology and the producer of the convention.

advice from the European Medicines Agency on Xanamem® development plans in Alzheimer's in the second quarter; and the topline final results of the XanaMIA trial due in November."

"Positive XanaMIA results will position Xanamem as unique and differentiated – the first oral therapy to convincingly slow or stabilize Alzheimer's decline."

Financial position

The Company incurred operating expenditure of \$6.5m during the December quarter as the XanaMIA clinical trial activity continued at a rapid pace with all 35 sites actively recruiting, culminating in the randomization and treatment of the final, 247th trial participant on 17 December 2025.

On 15 October 2025, the Company received a research and development tax incentive (RDTI) rebate of \$5.5m from the Australian Tax Office (ATO) for the 2025 financial year. After repaying a \$3.2m loan (including interest) received on 30 June 2025 from Endpoints Capital secured against the FY25 RDTI, the net cash inflow was \$2.3m.

The Company is currently awaiting receipt from the ATO of a further RDTI rebate of \$1.9m relating to an approved Advanced Overseas Finding application for the 2025 financial year.

On 27 January 2026, the Company announced that it had further strengthened its balance sheet through the receipt of a second tranche of non-dilutive funding from Endpoints Capital for \$4.3m secured against the Company's forecast FY26 RDTI rebate.

Consistent with ASX Listing Rule 4.7c.3, item 6 of the attached Appendix 4C of the cashflow report for the quarter included payments to Related Parties of \$0.2m, comprising the salary for the CEO/Managing Director, fees paid to Non-Executive Directors, and superannuation.

View this announcement on our InvestorHub: <https://investors.actinogen.com.au/link/epJ69P>

ENDS

Investors

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

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 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. The trial is now closed to recruitment, with final topline results 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, 11 β -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 11 β -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.

Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity

ACTINOGEN MEDICAL LIMITED

ABN

14 086 778 476

Quarter ended ("current quarter")

31 December 2025

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
1 Cash flows from operating activities		
1.1 Receipts from customers	-	-
1.2 Payments for		-
(a) research and development	(5,125)	(9,434)
(b) product manufacturing and operating costs		-
(c) advertising and marketing		-
(d) leased assets		-
(e) staff costs	(1,001)	(2,612)
(f) administration and corporate costs	(484)	(1,092)
1.3 Dividends received (see note 3)		-
1.4 Interest received	106	233
1.5 Interest and other costs of finance paid	(8)	(15)
1.6 Income taxes paid		-
1.7 Government grants and tax incentives		-
1.8 Other (working capital movements)	(30)	278
1.9 Net cash from / (used in) operating activities	(6,542)	(12,642)
2 Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	-	(3)
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	-
2.2 Proceeds from disposal of:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	-	-
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	-
2.3 Cash flows from loans to other entities	-	-
2.4 Dividends received (see note 3)	-	-
2.5 Other (provide details if material)	5,490	5,490
2.6 Net cash from / (used in) investing activities	5,490	5,487

3 Cash flows from financing activities		
3.1 Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
3.2 Proceeds from issue of convertible debt securities	-	-
3.3 Proceeds from exercise of options	319	331
3.4 Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5 Proceeds from borrowings	-	-
3.6 Repayment of borrowings	-	-
3.7 Transaction costs related to loans and borrowings (repayment of RDTI Loan)	(3,149)	(3,149)
3.8 Dividends paid	-	-
3.9 Other (application for exercise of options not yet allotted)	-	-
3.10 Net cash from / (used in) financing activities	(2,830)	(2,818)
4 Net increase / (decrease) in cash and cash equivalents for the period		
4.1 Cash and cash equivalents at beginning of period	10,413	16,504
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(6,542)	(12,642)
4.3 Net cash from / (used in) investing activities (item 2.6 above)	5,490	5,487
4.4 Net cash from / (used in) financing activities (item 3.10 above)	(2,830)	(2,818)
4.5 Effect of movement/adjustment in exchange rates on cash held	-	-
4.6 Cash and cash equivalents at end of period	6,531	6,531
5 Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter \$A'000	Previous quarter \$A'000
5.1 Bank balances	2,531	3,113
5.2 Call deposits	4,000	7,300
5.3 Bank overdrafts	-	-
5.4 Other	-	-
5.5 Cash and cash equivalents at end of quarter (should equal item 4.6 above)	6,531	10,413
6 Payments to related parties of the entity and their associates	Current quarter \$A'000	
6.1 Aggregate amount of payments to related parties and their associates included in item 1	204	
6.2 Aggregate amount of payments to related parties and their associates included in item 2	0	
<i>Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.</i>		
Payments relate to salaries & fees paid to Directors of the Company during the quarter.		

<p>7 Financing facilities</p> <p><i>Note: the term “facility” includes all forms of financing arrangements available to the entity.</i></p> <p><i>Add notes as necessary for an understanding of the sources of finance available to the entity.</i></p> <p>7.1 Loan facilities</p> <p>7.2 Credit standby arrangements</p> <p>7.3 Other (please specify)</p> <p>7.4 Total financing facilities</p> <p>7.5 Unused financing facilities available at quarter end</p> <p>Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.</p>	<p>Total facility amount at quarter end \$A'000</p>	<p>Amount drawn at quarter end \$A'000</p>
	-	-
	-	-
	-	-
	-	-
		-

8	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(6,542)
8.2	Cash and cash equivalents at quarter end (item 4.6)	6,531
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	6,531
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	1.00
	<p><i>Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as “N/A”. Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.</i></p>	
8.6	<p>If item 8.5 is less than 2 quarters, please provide answers to the following questions:</p> <p>8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?</p> <div style="border: 1px solid black; padding: 5px; margin: 5px 0;"> <p>Answer: Yes, the Company will have current level of cash flows similar to the December 2025 quarter and anticipates being able to fund these as described below.</p> </div> <p>8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?</p> <div style="border: 1px solid black; padding: 5px; margin: 5px 0;"> <p>Answer: Post-quarter end, the Company has received \$4.3m in loan funding from Endpoints Capital secured against its FY26 RDTI and is expected to receive a further \$1.9M of RDTI rebate related to eligible R&D expenditure incurred in FY25. The Company also has access to other sources of capital through the ongoing conversion of outstanding options, potential partnership transactions, further R&D loan funding or further equity raising.</p> </div> <p>8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?</p> <div style="border: 1px solid black; padding: 5px; margin: 5px 0;"> <p>Answer: Yes, the Company has access to funding as described above.</p> </div> <p><i>Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.</i></p>	

Compliance statement

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

Date: 30 January 2026

Authorised by: By the Board
(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.
4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [*name of board committee – eg Audit and Risk Committee*]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.