



ASX ANNOUNCEMENT

Actinogen June 2026 quarterly activity report and Appendix 4C

Sydney, 30 July 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 30 June 2026.

Highlights:

- Pivotal Alzheimer’s disease trial remains on track for topline final results in November this year with third positive independent Data Monitoring Committee (DMC) recommendation
- Strong ongoing enrolment in open-label extension (OLE) phase of the trial with 88% of main trial participants choosing to immediately continue in the OLE where they receive active Xanamem® therapy
- Positive scientific advice received from the European Medicines Agency generally aligned with prior US FDA advice
- Peer-reviewed depression trial manuscript detailing positive anti-depressant activity published in *British Journal of Psychiatry*
- The first national acceptances received for new patents covering Xanamem treatment of cognitive decline in healthy elderly persons and key manufacturing steps
- June-end cash balance of \$16.7m provides cash runway beyond XanaMIA trial final results to mid-2027.

Pivotal XanaMIA phase 2b/3 Alzheimer’s disease (AD) trial remains on track for topline results in November

- The Company’s pivotal XanaMIA phase 2b/3 Alzheimer’s disease trial continued to progress during the quarter, with treatment and follow-up activities proceeding as planned across participating clinical sites. The trial remains fully enrolled and on track to deliver topline results in November this year
- In June, the Company’s independent DMC completed another formal review of accumulating trial safety data from all 247 participants and recommended that the trial continue without amendment. This marks the third positive DMC recommendation received during the XanaMIA trial and provides further support for the ongoing conduct of the trial
- Preparations are underway for follow-on regulatory interactions and development activities that will allow the Company to move confidently into the final pivotal trial of Xanamem in AD if XanaMIA topline results are positive in November.

XanaMIA AD trial open-label extension advances

- Enrolment in the OLE phase of the XanaMIA Alzheimer’s disease trial advanced substantially during the quarter after commencement on 31 March 2026. There are now 81 patients on treatment, with an 88% rollover rate for participants completing the main trial and commencing the OLE
- The OLE enables all current and former participants, who have completed the randomized phase of the pivotal XanaMIA AD trial, the opportunity to receive active Xanamem 10 mg once daily for up to 25 months, with no placebo control group
- This long-term extension is designed to provide access to active Xanamem therapy for all randomized trial participants and gather extended safety data and observational information on key efficacy endpoints —

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including CDR-SB,¹ cognition, and activities of daily living. Trial data will provide a valuable contribution to future regulatory marketing applications.

Positive scientific advice received from the European Medicines Agency (EMA)

- In late May, the Company announced a successful outcome from its scheduled scientific advice interaction with the EMA, establishing a common understanding regarding the pathway to marketing approval of Xanamem in Alzheimer's disease within the European Union
- Key understandings included:
 - Agreement on the suitability of regulatory starting materials for commercial manufacturing of Xanamem drug substance
 - The design of one additional pivotal (phase 3) trial following a positive XanaMIA outcome
 - The proposed safety database requirements expected to support a future marketing authorisation application
 - A limited number of ancillary clinical pharmacology and non-clinical studies to be conducted in parallel with future development activities.
- The common understandings reached on numerous matters with the FDA's Neurology-I Division in 2025 and now the EMA, mark significant milestones for the Company as it prepares for the earliest possible global marketing submissions and approvals
- For planning purposes, the Company continues to assume it will need to conduct a second pivotal trial as described above. Pending pivotal trial results in November, Actinogen will explore the opportunity to seek regulatory approvals based on one pivotal trial instead of two
- The regulatory agreements and feedback received from the FDA and EMA also support commercial and partnering discussions by providing external validation of Xanamem's late-stage development pathway and the feasibility of an efficient route to marketing approvals in key jurisdictions.

Peer-reviewed manuscript showing Xanamem anti-depressant activity published in the *British Journal of Psychiatry*

- On 20 July, the Company announced that results from its phase 2 proof-of-concept trial of Xanamem (emestedastat) in patients with major depressive disorder (MDD) and cognitive impairment (CI) had been published in the *British Journal of Psychiatry*, a leading international peer-reviewed journal
- The publication reports encouraging evidence of anti-depressant activity with Xanamem in a difficult-to-treat population and supports further clinical development as a novel therapy for MDD
- In the trial, Xanamem demonstrated a clinically, and at times statistically, significant improvement in depression scores versus placebo, with the greatest effect observed at the end of the blinded follow-up period,² with the strongest response in patients receiving background standard-of-care antidepressant treatment. No treatment benefit was observed on cognitive measures, potentially reflecting a higher-than-expected placebo response and the marked improvement seen in both groups
- Xanamem was safe and well tolerated, consistent with safety data from multiple other trials.

Commercial planning and partnering activities

- The Company continued to advance its commercial and partnering readiness as the Xanamem program progresses toward potentially transformational pivotal trial results in November. Activities this quarter included continued engagement with Alzheimer's disease key opinion leaders at conferences and via direct communications, with an emphasis on educating them on the strong scientific rationale for Xanamem's cortisol control mechanism of action and the high quality of previous clinical trial data
- Interest from potential commercialization partners with global and/or regional marketing reach continues to grow as pivotal trial results approach. Discussions remain focussed on ensuring potential partners are

¹ CDR-SB is the Clinical Dementia Rating Scale – Sum of Boxes

² The delayed onset of effect is consistent with the known biology of cortisol modulation

well-positioned to rapidly evaluate the opportunity prior to and immediately after XanaMIA results become available.

Intellectual property protection from future generic competition

- The Company continued to prosecute a variety of new patents in the quarter covering use of Xanamem in treating cognitively normal people and patients with depression, manufacturing methods, tablet formulation and patient selection methods
- The first national acceptances were received for new patents covering Xanamem treatment of cognitive decline in healthy elderly persons (Australia, Russia) and Xanamem manufacturing processes (China, Chile, Russia)
- Additionally, the Chinese government announced enactment of a new six-year “data exclusivity” provision which means that Xanamem, as a novel and innovative drug in China, would be potentially protected from generic competitors for a period of at least six years from marketing approval by this mechanism.

Presented at international and Australian conferences

- In mid-July, CEO, Dr Steven Gourlay, was joined in London by Chief Medical Officer, Dr Dana Hilt, Chief Commercial officer Andy Udell, and Senior Clinical Scientist Dr Jack Taylor at the Alzheimer’s Association International Conference (AAIC). They presented an academic poster highlighting screening efficiency and baseline population characteristics from the fully enrolled XanaMIA phase 2b/3 trial of Xanamem in patients with mild to moderate AD. While at the conference, the team also participated in industry, analyst and investor meetings. Industry engagement was active and constructive, with interest from a broad spectrum of parties
- In June, the Company presented a similar academic poster at the Australian Dementia Network’s Australian Dementia Research Forum (ADRF) in Sydney. The team held a number of meetings with key Australian and international thought leaders in Alzheimer’s disease during the forum.

Finances – June cash position provides cash runway to mid-2027

- The company ended the June quarter with \$16.7 million of cash on hand, providing cash runway until mid-2027, well beyond the release of topline final XanaMIA trial results in November 2026. Further cash receipts are expected from the R&D tax rebate later in 2026 (net of R&D loan repayments) and potential exercise of options
- Operating expenditure of \$5.0 million was incurred during the June quarter, with the majority of spend associated with the XanaMIA clinical trial and associated with the robust participation in the OLE phase of the trial
- 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 \$0.2 million, comprising the salary for the CEO/Managing Director, fees paid to Non-Executive Directors, and superannuation.

Actinogen CEO and MD, Dr Steven Gourlay said:

“The June quarter was a busy period for the Company with a number of important achievements.

“We are particularly proud of the positive anti-depressant activity detailed in the recent British Journal of Psychiatry publication as this strongly validates the clinical activity in the brain of the Xanamem 10 mg dose. Anti-depressant activity would be a welcome feature of a new Alzheimer’s treatment and major depressive disorder itself is a potential development program for Xanamem.

“In addition, we saw continued success across clinical, regulatory and commercial planning areas as we advance towards pivotal XanaMIA Alzheimer’s disease topline results in November.”

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

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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 ([Taylor et. al. 2026](#)) 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 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.

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")

30 June 2026

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
1 Cash flows from operating activities		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(3,727)	(19,316)
(b) product manufacturing and operating costs		-
(c) advertising and marketing		-
(d) leased assets		-
(e) staff costs	(1,077)	(4,712)
(f) administration and corporate costs	(469)	(1,993)
1.3 Dividends received (see note 3)		-
1.4 Interest received	163	500
1.5 Interest and other costs of finance paid	(7)	(179)
1.6 Income taxes paid		-
1.7 Government grants and tax incentives	-	7,346
1.8 Other (working capital movements)	133	560
1.9 Net cash from / (used in) operating activities	(4,984)	(17,794)
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)	-	-
2.6 Net cash from / (used in) investing activities	-	(3)

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

3 Cash flows from financing activities		
3.1 Proceeds from issues of equity securities (excluding convertible debt securities)	-	16,772
3.2 Proceeds from issue of convertible debt securities	-	-
3.3 Proceeds from exercise of options	246	778
3.4 Transaction costs related to issues of equity securities or convertible debt securities	(37)	(851)
3.5 Proceeds from borrowings	-	4,320
3.6 Repayment of borrowings	-	(3,000)
3.7 Transaction costs related to loans and borrowings	-	-
3.8 Dividends paid	-	-
3.9 Other (application for exercise of options not yet allotted)	-	-
3.10 Net cash from / (used in) financing activities	209	18,019
4 Net increase / (decrease) in cash and cash equivalents for the period		
4.1 Cash and cash equivalents at beginning of period	21,501	16,504
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(4,984)	(17,626)
4.3 Net cash from / (used in) investing activities (item 2.6 above)	-	5,487
4.4 Net cash from / (used in) financing activities (item 3.10 above)	209	(2,609)
4.5 Effect of movement/adjustment in exchange rates on cash held	-	-
4.6 Cash and cash equivalents at end of period	16,726	1,756
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	2,726	7,501
5.2 Call deposits	14,000	14,000
5.3 Bank overdrafts	-	-
5.4 Other	-	-
5.5 Cash and cash equivalents at end of quarter (should equal item 4.6 above)	16,726	21,501
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.		

7 Financing facilities <i>Note: the term "facility" includes all forms of financing arrangements available to the entity.</i> <i>Add notes as necessary for an understanding of the sources of finance available to the entity.</i> 7.1 Loan facilities 7.2 Credit standby arrangements 7.3 Other (please specify) 7.4 Total financing facilities	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
	4,320	-
	-	-
	-	-
	4,320	-
7.5 Unused financing facilities available at quarter end		
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. In the previous quarter, the Company borrowed \$4.32m in non-dilutive funding from Endpoints Capital under a funding facility secured against the Company's FY26 Research and Development Tax Incentive ("RDTI"). The interest rate is 15.1% per annum and repayment is the earlier of either: the date that the FY26 R&D Refund is received or the applicable maturity date, this being 31 December 2026.		

8 Estimated cash available for future operating activities	\$A'000
8.1 Net cash from / (used in) operating activities (item 1.9)	(4,984)
8.2 Cash and cash equivalents at quarter end (item 4.6)	16,726
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	16,726
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	3.36
<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>	
8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:	
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?	
Answer:	
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?	
Answer:	
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?	
Answer:	
<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>	

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 July 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.