ASX ANNOUNCEMENT

September 2021 Quarterly Activity Report and Appendix 4C

Sydney, 20 October 2021. 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 September 2021.

Key highlights:

- **Advancing the Xanamem® clinical development pipeline:**
  - Part A of the two-part XanaMIA trial in Mild Cognitive Impairment (MCI) due to Alzheimer's Disease (AD) commenced in healthy older volunteers with more than 50% of the planned 105 participants enrolled during the quarter
  - XanaFX trial in adolescent patients with Fragile X Syndrome (FXS), addressing cognition, anxiety, sleep and behavioural problems to commence as planned in 2H CY21 under a US FDA Investigational New Drug (IND) regulatory approval
  - A third disease indication, adding further diversification to the Phase 2 program, to be announced in the current (December) quarter
- **Filed Investigational New Drug (IND) submission to the US FDA for FXS program**
- **Received notification from the Brazilian Patent and Trademark Office of grant of patent application for Xanamem**
- **Cash balance of A$11.82 million at 30 September 2021**
- **R&D tax incentive rebate of A$1.43 million received subsequent to quarter-end.**

Advancing the clinical development pipeline through multiple clinical trials

Actinogen remains focused on excellent clinical development, designed to deliver "multiple shots on goal" with timely and high-quality confirmation of clinical efficacy and safety in each of its disease programs. The Company is conducting its lead programs under a US Investigational New Drug (IND) process to ensure the highest standards of regulatory compliance for clinical development, non-clinical studies and manufacturing.

Alzheimer's Disease Program – XanaMIA Trial

The enrolment of the first patient in Part A of the XanaMIA trial was announced on 15 July 2021.

This trial seeks to assess the efficacy of 5mg and 10mg Xanamem doses on cognition (ability to remember and think) compared to placebo in 105 older healthy patients (aged 50 to 80 years old), over six weeks, to confirm the minimum effective dose. It is being conducted at four[1] outpatient sites in Australia. This trial will use the Cogstate Neuropsychological Test Battery, supplemented by the Digit Symbol Substitution Test (iDSST) which has been recognised in the past by the FDA as an appropriate endpoint for a cognitive marketing claim.

Enrolment was approximately 55% complete at the end of September and exceeds 65% at the date of this announcement. It is expected to be completed during the current (December) quarter.

® Xanamem is a registered trademark of Actinogen Medical Limited.

[1] Subsequent to the end of the quarter a second site was added in Queensland, taking the total active sites to five to mitigate the potential risk of slower than expected enrolments at NSW sites due to COVID-19 restrictions.

Part B of the XanaMIA trial will be informed by the results of Part A and will investigate the efficacy of Xanamem in patients with positive AD biomarkers. Part B will measure the effects of Xanamem on biomarkers indicative of the underlying disease processes in addition to endpoints related to cognition.

The XanaMIA trial Part A will read out in 1H CY22 and Part B approximately a year later in 2023.

Fragile X Syndrome (FXS) Program – XanaFX Trial

Our "Fast-to-Market" XanaFX program has taken its next step with the successful filing of the IND to the US FDA as planned during September 2021. We are awaiting FDA approval that will ensure that the trial incorporates all requirements and is of an international regulatory standard. The FDA and the Company are also in agreement on the proposed Phase 2 adolescent patient population to be studied.

We are well advanced with the planning for the Phase 2 XanaFX trial for cognition, anxiety, sleep and behavioural problems in Fragile X Syndrome. There are currently no approved treatment options that specifically target these symptoms associated with FXS which have a substantial impact on the day-to-day functioning of patients and their caregivers. The trial will commence at Australian specialist hospital clinics and will study 50 patients. It will be a randomised, placebo-controlled, double-blind, 12-week trial investigating the safety and efficacy of Xanamem in male adolescents and young adults possessing the full genetic features associated with FXS.

Third Indication Program – to be announced

Actinogen continues to examine a range of potential indications to add to our clinical development pipeline. We expect to announce the addition of a third target indication in the current (December) quarter, with commencement of the Phase 2 trial in 2022.

Dr Steven Gourlay, Actinogen CEO and MD, commented:

"The team has done an excellent job of advancing the clinical trials for Xanamem in our lead indications of Alzheimer's Disease and Fragile X Syndrome – both serious and debilitating conditions with a high unmet medical need. The XanaMIA trial is recruiting well, despite the COVID pandemic, and the XanaFX trial preparation is progressing as planned, with the positive pre-IND FDA advice providing guidance and support for our planned program."

Intellectual property

ACW received official notification in late August 2021 from the Brazilian Patent and Trademark Office of grant of its patent application for Xanamem. The grant of the Brazilian patent completes a key part of Actinogen's intellectual property portfolio, with protection across all major pharmaceutical markets including the USA, UK, EU, Japan, China, Canada and Australia. The patents provide exclusive rights in these regions and cover the composition of matter of Xanamem and its use in all diseases including AD and FXS.

Globally, this patent encompasses composition of matter protection to 2031 with the possibility to extend by an additional 5 years in markets including Australia, the US, the EU, Korea, Japan, China, and Israel.

Cash position

Actinogen's cash balance as at 30 September 2021 was A$11.82 million. Net operating cash outflow for the quarter was A$1.64 million, mostly related to R&D spend of A$0.76 million, staff costs of A$0.46 million and administration and corporate costs of A$0.40 million. The cash balance does not include the A$1.43 million R&D tax incentive rebate received after the end of the September quarter. The Company remains well positioned to fund its current planned clinical trials and advance clinical development.

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 approximately A$0.16 million, comprising the salary for the CEO/Managing Director, fees paid to Non-Executive Directors and superannuation.

ENDS

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

Michael Roberts
Investor Relations
P: +61 2 8964 7401
E: michael.roberts@actinogen.com.au

Announcement authorised by the Board of Directors of Actinogen Medical

About Actinogen Medical

Actinogen Medical (ASX:ACW) is an ASX-listed biotechnology company developing novel therapies for neurological diseases associated with dysregulated brain cortisol. The Company is currently developing its lead compound, Xanamem®, as a promising new therapy for Alzheimer's Disease, Fragile X Syndrome, and other potential neurological diseases. The cognitive dysfunction, behavioural abnormalities, and neuropsychological burden associated with these conditions is significantly debilitating for patients, and there is a substantial unmet medical need for new and improved treatments.

About Xanamem®

Xanamem's novel mechanism of action works by blocking the production of intracellular cortisol – the stress hormone – through the inhibition of the 11β-HSD1 enzyme in the brain. There is a strong association between persistent stress and the production of excess cortisol that leads to detrimental changes in the brain, affecting memory, cognitive function and behaviour and neuropsychological symptoms.

The Company has studied 11β-HSD1 inhibition by Xanamem in approximately 300 volunteers and patients, finding a statistically significant improvement in cognition over placebo in healthy, older volunteers. A series of Phase 2 studies in multiple indications will be conducted to further confirm and characterise Xanamem's efficacy and safety.

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 based on subjective estimates and assumptions and relate to circumstances and events that have not taken place and may not take place. Such forward looking statements involve known and unknown risks, uncertainties, and other factors (such as significant business, economic and competitive uncertainties and contingencies, and regulatory and clinical development risks and uncertainties) which may cause the actual results or the performance of Actinogen Medical to be materially different from the results or performance expressed or implied by such forward looking statements. Past performance is not a reliable indicator of future performance. There can be no assurance that any forward-looking statements will be realised. Actinogen Medical does not make any representation or give any warranty as to the likelihood of achievement or reasonableness of any forward-looking statements.

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	**Quarter ended ("current quarter")**
14 086 778 476	30 September 2021

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (3 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers		
1.2	Payments for		
	(a) research and development	(762)	(762)
	(b) product manufacturing and operating costs		
	(c) advertising and marketing		
	(d) leased assets		
	(e) staff costs	(462)	(462)
	(f) administration and corporate costs	(401)	(401)
1.3	Dividends received (see note 3)		
1.4	Interest received	8	8
1.5	Interest and other costs of finance paid	(4)	(4)
1.6	Income taxes paid		
1.7	Government grants and tax incentives		
1.8	Other (office lease)	(17)	(17)
1.9	**Net cash from / (used in) operating activities**	**(1,638)**	**(1,638)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities		
	(b) businesses		
	(c) property, plant and equipment		
	(d) investments		
	(e) intellectual property		
	(f) other non-current assets		

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 months) $A'000
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.	**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		
3.4	Transaction costs related to issues of equity securities or convertible debt securities		
3.5	Proceeds from borrowings		
3.6	Repayment of loan shares by Managing Director		
3.7	Transaction costs related to loans and borrowings		
3.8	Dividends paid		
3.9	Other		
3.10	**Net cash from / (used in) financing activities**	**-**	**-**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	13,457	13,457
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,638)	(1,638)
4.3	Net cash from / (used in) investing activities (item 2.6 above)		

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)		
4.5	Effect of movement in exchange rates on cash held		
4.6	**Cash and cash equivalents at end of period**	**11,819**	**11,819**

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	4,784	6,422
5.2	Call deposits	7,000	7,000
5.3	Bank overdrafts		
5.4	Other – restricted cash re office lease	35	35
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	11,819	13,457

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	158
6.2	Aggregate amount of payments to related parties and their associates included in item 2	

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.

7.	**Financing facilities** *Note: the term "facility' includes all forms of financing arrangements available to the entity.* *Add notes as necessary for an understanding of the sources of finance available to the entity.*	**Total facility amount at quarter end $A'000**	**Amount drawn at quarter end $A'000**
7.1	Loan facilities		
7.2	Credit standby arrangements		
7.3	Other (please specify)		
7.4	**Total financing facilities**		

7.5	**Unused financing facilities available at quarter end**	
7.6	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.	

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(1,638)
8.2	Cash and cash equivalents at quarter end (item 4.6)	11,819
8.3	Unused finance facilities available at quarter end (item 7.5)	
8.4	Total available funding (item 8.2 + item 8.3)	11,819
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	7.22

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.

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: N/A

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: N/A

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: N/A

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.

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: 20 October 2021

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.