ASX ANNOUNCEMENT

June 2021 Quarterly Activity Report & Appendix 4C

Key highlights:

- **Advancing the Xanamem® clinical development pipeline, with fully funded Phase II trials:**
  - Two-part XanaMIA trial in Mild Cognitive Impairment (MCI) due to Alzheimer's disease (AD) has commenced in healthy older volunteers and patients with biomarker-confirmed AD
  - XanaFX trial in adolescent patients with Fragile X syndrome (FXS), addressing anxiety, sleep and behavioural problems to commence in 2H CY21
  - Third indication to be announced in 2H CY21
- **Commenced Part A XanaMIA trial subsequent to the quarter, following Bellberry Human Research Ethics Committee (HREC) approval**
- **Signed work orders to engage Avance Clinical and Paratus Clinical to assist in XanaMIA trial**
- **Received positive Pre-Investigational New Drug (Pre-IND) feedback advice from the FDA for FXS program**
- **Strong cash position with A$13.46m held as at 30 June 2021**

Sydney, 22 July 2021. Actinogen Medical ASX: ACW ('Actinogen' or 'the Company') today submitted its quarterly activity report and Appendix 4C for the three-month period ended 30 June 2021.

Advancing clinical development, with multiple clinical trials planned

The success of the Phase I XanaHES study cognition data in healthy older patients will be leveraged into an Alzheimer's population, with a two-part Phase II XanaMIA trial advancing in healthy, older volunteers and patients with MCI due to AD. Subsequent to the quarter, Actinogen announced the commencement of Part A of the XanaMIA study, with the first volunteer treated in the trial. This study seeks to assess the efficacy of 5mg and 10mg Xanamem doses compared to placebo in 105 older healthy patients (aged 50 to 80 years old), over 6 weeks, to confirm the minimum effective dose. Part B will be informed by the results of Part A and will investigate the efficacy of Xanamem in patients with MCI confirmed by the presence of positive biomarkers in the blood to be due to early-stage AD. This study will utilise 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.

In parallel, Actinogen remains focused on progressing the study plan for anxiety, sleep and behavioural problems in Fragile X Syndrome (FXS). 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 caretakers. The study will be conducted in Australia, and is a randomised, placebo-controlled, double-blind, 12-week trial investigating the safety and efficacy of Xanamem in male adolescents suffering from FXS. Actinogen is well advanced with the planning for its Phase II XanaFX trial, which is expected to commence in 2H CY21.

Actinogen expects to announce the addition of a third target indication to the clinical development pipeline in 2H CY21.

Commenced XanaMIA trial following ethics approval and signed work orders

Subsequent to the quarter, Actinogen announced that the first patient had been enrolled in Part A of the XanaMIA trial, following Bellberry Human Research Ethics Committee approval during the quarter. This marked a significant milestone in the progression of Actinogen's AD program. During the quarter, Actinogen also signed agreements with Avance Clinical and Paratus Clinical to manage and assist in the XanaMIA study. Avance Clinical has been appointed as Contract Research Organisation to manage the study while Paratus will be managing all subject recruitment activities across four sites in Australia. Actinogen also finalised a work order with Cogstate in April to utilise its Neuropsychological Test Battery.

Received positive Pre-IND FDA advice for FXS program

During the quarter, Actinogen received positive US FDA advice in response to a Pre-IND submission for its FXS program. The advice indicates that the data package and trial design proposed for the IND submission would be sufficient, subject to final review of all supportive documentation submitted. FDA approval 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 II adolescent patient population to be studied.

Dr Steven Gourlay, Actinogen CEO and MD, commented:

"Actinogen is advancing the development of Xanamem in the treatment of serious and debilitating conditions with a high unmet medical need. We are well-placed to fully fund our planned Phase II clinical trials from existing cash reserves. The XanaMIA trial has now commenced recruitment and the XanaFX trial preparation is progressing as planned, with the positive pre-IND FDA advice providing guidance and FDA support for our planned programme.

Actinogen continues to strengthen its commercialisation strategy by expanding the clinical development pipeline, actively engaging with potential future partners on a regular basis and seeking strong academic and grant collaborations. We are focused on building the Xanamem dataset and optimising manufacturing processes to prepare for commercialisation."

Strong cash position

Actinogen's cash balance as at 30 June 2021 was A$13.46m. Net operating cash outflows for the quarter was A$1.74m, mostly related to R&D spend of A$1.12m, staff costs of A$0.36m and administration and corporate costs of A$0.34m. Actinogen is now well positioned to fund its planned clinical trials and advance clinical development.

In line with 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$0.16m is comprised of the salary for the CEO/Managing Director, fees paid to the Non-Executive Directors and superannuation.

ENDS

Actinogen Medical

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Announcement authorised by the Board of Directors of Actinogen Medical

About Actinogen Medical

Actinogen Medical (ACW) is an ASX-listed, biotechnology company developing an innovative treatment for cognitive impairment associated with neurological diseases amenable to modifications of raised cortisol levels inside brain cells. 'Cognition' relates to how a person understands and acts in the world around them. Cognitive functions include memory, reasoning, awareness and decision-making, and to a large extent, influence our personality.

Actinogen Medical's lead drug candidate, **Xanamem®,** has been specifically designed to block the production of cortisol – the stress hormone – in the brain. Chronically elevated cortisol is associated with cognitive decline in **Alzheimer's Disease**, potentially linked to cognitive impairment and anxiety in **Fragile X syndrome**, and cognitive impairment in neuropsychiatric diseases.

Xanamem offers a promising new approach to treat cognitive impairment associated with these neurological diseases. In the Company's recent XanaHES Phase I trial, Xanamem exhibited a statistically significant improvement in cognition among healthy older volunteers, and recent human target engagement data for the drug in the brain suggests good activity of doses as low as 5mg daily. The Company plans to initiate a range of Phase II studies evaluating Xanamem in the treatment of cognitive impairment associated with Alzheimer's disease, Fragile X syndrome, and other indication(s) with a strong scientific rationale.

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 registered 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.

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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 June 2021

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	(1,123)	(1,925)
	(b) product manufacturing and operating costs		
	(c) advertising and marketing		
	(d) leased assets	-	-
	(e) staff costs	(357)	(1,696)
	(f) administration and corporate costs	(337)	(1,103)
1.3	Dividends received (see note 3)		
1.4	Interest received	5	27
1.5	Interest and other costs of finance paid	(5)	(22)
1.6	Income taxes paid		
1.7	Government grants and tax incentives	77	3,029
1.8	Other (Miscellaneous, GST)	-	(28)
1.9	**Net cash from / (used in) operating activities**	**(1,740)**	**(1,718)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities		
	(b) businesses		
	(c) property, plant and equipment	-	(6)
	(d) investments		
	(e) intellectual property		
	(f) other non-current assets		

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 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**	**-**	**(6)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	10,911
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	(11)	(716)
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 (principal payment on office lease)	(26)	(90)
3.10	**Net cash from / (used in) financing activities**	**(37)**	**10,105**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	15,234	5,076
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,740)	(1,718)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	(6)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(37)	10,105
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**13,457**	**13,457**

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	6,422	13,199
5.2	Call deposits	7,000	2,000
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)**	**13,457**	**15,234**

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	162
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)	(1,740)
8.2	Cash and cash equivalents at quarter end (item 4.6)	13,457
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	13,457
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	7.73

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: 22 July 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.