ASX ANNOUNCEMENT

March 2021 Quarterly Activity Report & Appendix 4C

Sydney, 21 April 2021. Actinogen Medical ASX: ACW ('ACW' or 'the Company') today submitted its quarterly activity report and Appendix 4C for the three-month period ended 31 March 2021.

Key highlights:

- **Xanamem™ clinical development plans progressing as planned, with two fully funded Phase II trials expected to commence in CY21:**
  - XanaMIA trial in patients with Mild Cognitive Impairment due to Alzheimer's disease
  - XanaFX trial in adolescent patients with Fragile X syndrome, addressing anxiety, sleep, and behavioural problems
- **Awarded Rare Paediatric Disease Designation for Xanamem in FXS by the US FDA**
- **Appointment of Dr. Steven Gourlay as Actinogen's new Chief Executive Officer and Managing Director,** bringing over 30 years of experience in the development of novel therapeutics
- **Strong cash position with A$15.23m held as at 31 March 2021**, including funds raised during the quarter from the Entitlement Offer Shortfall Placement (A$3.55m)

Advancing clinical development – planning for multiple clinical trials

Actinogen continues to focus on the development of its lead drug, Xanamem, as a treatment for multiple indications. The Company is leveraging the positive Phase I XanaHES results, in which a significant improvement in multiple cognition domains was achieved in healthy older volunteers, into an Alzheimer's population with a Phase II XanaMIA trial planned to target patients with mild cognitive impairment (MCI) due to Alzheimer's Disease (AD). The Phase I trial achieved efficacy results with the Cogstate Cognitive Test Battery ('Cogstate'), a sensitive and modern testing tool, which can now be used in future studies. The XanaMIA trial is expected to commence in CY21.

In parallel, Actinogen remains focused on progressing study planning for anxiety, sleep and behavioural problems in Fragile X syndrome (FXS). These symptoms have a substantial impact on day-to-day functioning of patients and their carers and there are currently no approved treatment options that specifically target these symptoms associated with FXS. Actinogen is well advanced with the planning for its Phase II XanaFX, with the trial expected to commence in H2 CY21. The trial will investigate the treatment of Xanamem in male adolescents (age 12-18) with FXS and will evaluate the safety and efficacy of Xanamem on dimensions of anxiety, sleep and behavioural problems.

For more information on the upcoming clinical studies and development plan, please refer to Actinogen's Strategic Update and Investor Presentation to be released today.

FDA awarded Rare Paediatric Disease Designation (RPDD) for Xanamem in FXS

During the quarter, Xanamem was awarded RPDD by the FDA for treatment of FXS in patients under the age of 18. The RPDD program is designed to incentivise the development of drugs for rare childhood illnesses, such as FXS, with potential clinical, development and commercial benefits. This includes priority review and therefore faster clinical development and commercialisation of Xanamem. In addition, if Xanamem is first registered in the US for FXS Actinogen may receive a Priority Review Voucher (PRV) from the FDA, which can

be used for different indications, and is also tradeable. Biopharma companies have historically sold PRVs for ~US$100m-US$125m in recent years, which highlights its substantial commercial potential to the Company.

New CEO and MD appointed, with a strong track record in drug development

During the quarter, Dr Bill Ketelbey resigned as Chief Executive Officer (CEO) and Managing Director (MD) of the Company, effective on 8 February 2021. Dr Ketelbey had been dedicated to developing Xanamem over the past six years, and his services and expertise have contributed significantly in advancing pre-clinical and clinical trials to generate the current body of knowledge on Xanamem. The Board of Directors thanks Dr Ketelbey for his valuable contribution to the Company.

Dr Steven Gourlay was appointed as Actinogen's new CEO on 15 March 2021 and subsequently assumed the role of MD on 24 March 2021. Dr Gourlay has more than 30 years of experience in the development of novel therapeutics and brings extensive knowledge of the biotech investment industry to the senior management team. Formerly the founding Chief Medical Officer (CMO) at US-based Principia Biopharma Inc., he was responsible for the supervision of multiple pre-clinical and clinical trials as well as its successful IPO in 2018. Principia was subsequently acquired by Sanofi Inc. for ~US$3.7B. His global background in drug development, regulatory affairs and commercial activities will all be valuable at Actinogen's current stage of development. As part of the shortfall placement completed in February 2021, prior to his appointment, Dr Gourlay invested in ~15m ACW shares at the A$0.022 offer price, alongside other professional and sophisticated investors, demonstrating his support of Actinogen's clinical development and outlook.

Strong cash position

Actinogen's cash balance as at 31 March 2021 was A$15.23m. Net operating cash outflows for the quarter was A$1.04m, mostly related to R&D spend of A$0.23m, staff costs of A$0.59m and administration and corporate costs of A$0.26m. In February 2021, Actinogen successfully raised a further ~A$3.55m, after raising A$7.36m from a placement and entitlement offer in the previous quarter. 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$0.40m is comprised of fees paid to the Non-Executive Directors, consulting fees and salary paid during the quarter to the new CEO/MD, and the salary and payments to the former Managing Director.

Outlook

Actinogen is advancing the development of Xanamem in the treatment of serious and debilitating conditions with a high unmet medical need, with plans for multiple phase II clinical trials to commence this year following relevant regulatory approvals. The strong cash position fully funds Actinogen's currently planned trials. The XanaMIA and XanaFX trials are both expected to commence this calendar year, with RPDD supporting further clinical development and commercialisation of Xanamem in FXS.

In addition, Actinogen continues to strengthen its commercialisation strategy by accelerating independent clinical development and targeting strategic value creating opportunities. This includes assessing other high priority indications to target and leveraging the potential for strong academic and grant collaborations. Actinogen will continue to build on its significant progress, with regulatory activities progressing in the lead up to the commencement of both trials.

ENDS

Actinogen Medical

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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 more than 200 volunteers and patients, finding a statistically significant improvement in cognition over placebo in healthy, older volunteers. A series of Phase II 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, Link Market Services.

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	31 March 2021

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (9 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers		
1.2	Payments for		
	(a) research and development	(234)	(802)
	(b) product manufacturing and operating costs		
	(c) advertising and marketing		
	(d) leased assets	-	-
	(e) staff costs	(596)	(1,339)
	(f) administration and corporate costs	(259)	(766)
1.3	Dividends received (see note 3)		
1.4	Interest received	6	22
1.5	Interest and other costs of finance paid	(5)	(17)
1.6	Income taxes paid		
1.7	Government grants and tax incentives	18	2,952
1.8	Other (Miscellaneous, GST)	27	(28)
1.9	**Net cash from / (used in) operating activities**	**(1,043)**	**22**

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

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 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)**	**(6)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	3,551	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	(194)	(705)
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)	(22)	(64)
3.10	**Net cash from / (used in) financing activities**	**3,335**	**10,142**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	12,948	5,076
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,043)	22
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(6)	(6)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	3,335	10,142
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**15,234**	**15,234**

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	13,199	10,913
5.2	Call deposits	2,000	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)**	**15,234**	**12,948**

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	402
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)	(1,043)
8.2	Cash and cash equivalents at quarter end (item 4.6)	15,234
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	15,234
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	14.6

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: 21 April 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.