ASX ANNOUNCEMENT

September 2020 Quarterly Activity Report & Appendix 4C

Sydney, 29 October 2020. Actinogen Medical ASX: ACW ('ACW' or 'the Company') today submitted its quarterly activity report and Appendix 4C for the three-month period ended 30 September 2020.

Key highlights:

- **Xanamem™ clinical development advancing, with plans to commence two new clinical trials in 1H CY21**
  - **XanaMIA phase II trial in patients with Mild Cognitive Impairment (MCI) due to Alzheimer's disease**
  - **XanaFX phase II trial in patients with Fragile X syndrome selected as a new target indication, addressing anxiety, sleep and behavioural problems**
- **Ongoing focus on business development activities, with new website launched to incorporate additional R&D content, and presentations made at numerous events and conferences**
- **Strengthened senior management team with the recent appointment of Mr. Jeff Carter as the Company's new Chief Financial Officer**
- **Strong cash position with A$4.3m held as at 30 September 2020, excluding funds received in October 2020 from the recently completed placement (~A$6.0m) and a R&D tax incentive rebate for FY20 (~A$2.9m)**
  - **Actinogen currently has a 1 for 5 non-renounceable entitlement offer open to raise up to a further ~A$4.9m from eligible shareholders**

Advancing clinical development plans for multiple trials

During the quarter, Actinogen completed a comprehensive analysis of the substantial clinical (human) and pre-clinical (animal) data sets for Xanamem and its pipeline of indications. The outcomes of the analysis have enabled the Company to define the key study parameters for the planned clinical studies, including dosing and patient characteristics.

Actinogen continues to primarily focus on the development of Xanamem as a treatment for Alzheimer's disease (AD). The Company is building on the positive **XanaHES** results, in which a significant improvement in multiple cognition domains was achieved in healthy elderly volunteers, by initiating a new Xanamem study in an AD patient population. The planned **XanaMIA** phase II clinical trial in patients with **Mild Cognitive Impairment (MCI) due to AD** is designed to demonstrate the safety, tolerability and efficacy of Xanamem 10mg twice daily in this early stage of the Alzheimer's disease spectrum. This patient population represents a significant unmet clinical need and commercial opportunity.

In parallel, Actinogen has made significant progress with plans for developing additional indications for Xanamem, by adding anxiety, sleep and behavioural problems in **Fragile X syndrome (FXS)** to the development pipeline. The selection of Fragile X syndrome follows significant clinical interest in evaluating Xanamem across a range of a medical conditions associated with raised cortisol. There are currently no approved treatment options that specifically target these symptoms associated with FXS. Both the pharmacological properties of Xanamem and the current understanding of FXS pathology strongly support Xanamem as a potential

treatment option for these symptoms. Actinogen is already well advanced with the planning for a phase II study in FXS patients, **XanaFX.** This double-blind placebo-controlled trial will investigate the treatment of Xanamem in ~40 male adolescents (age 12-18) with FXS. The trial will be conducted by the Murdoch Children's Research Institute and the Royal Children's Hospital. The study is **fully funded** and expected to commence in 1H CY21

Importantly, Xanamem in FXS potentially meets the FDA criteria for **Orphan Drug Designation (ODD) and Rare Paediatric Disease Designation (RPDD)**. ODD and RPDD provide multiple incentives in many major markets including attractive development, regulatory and commercial benefits that could result in faster clinical development and commercialisation of Xanamem.

Subsequent to the quarter, Dr. Bill Ketelbey presented an update on Actinogen's clinical development during a conference call on 19 October, including further details on the **XanaMIA** and **XanaFX** trials. A recording of the webcast presentation can be found on Actinogen's website through this link: https://actinogen.com.au/investor-centre/#investor-updates

Ongoing business development activities and engagement with commercial and strategic parties

In July, Professor Craig Ritchie presented a poster on behalf of Actinogen at the Alzheimer's Association International Conference (AAIC). Additionally, Dr. Bill Ketelbey was interviewed by Innovation Intelligence International, with an article published highlighting the potential of a new Alzheimer's disease treatment, titled '*Alzheimer's treatment could be worth $10bn annually'*. Dr. Ketelbey also gave presentations to update shareholders and the investment community, including the Finance News Network (FNN) on Tuesday 28 July and a pre-recorded presentation as part of the ASX Small & Mid-Cap Conference on 8-10 September 2020.

In October, Actinogen launched an updated corporate website to ensure the latest Xanamem research and development information is available and accessible for investors, collaborators and other strategic parties. The site includes the additional indications added to Actinogen's clinical development pipeline with the latest information on MCI due to AD, FXS, schizophrenia and diabetes, and can be accessed at: https://actinogen.com.au/research-development/. Additionally, the Investor Centre section now includes Corporate Presentations, Financial Reports, Investor Updates and Media, including News, Interviews & Podcasts, Videos, Newsletters and Events, and can be accessed at: https://actinogen.com.au/investor-centre/.

The Actinogen team continues to progress with drafting numerous medical journal publications related to the Company's pre-clinical and clinical trials, and other areas of associated research. These publications represent important scientific and academic endorsement of the Company's research and will promote further awareness of the compelling results achieved to date with the development of Xanamem.

Corporate: Strengthened management team

In September 2020, Actinogen appointed Mr. Jeff Carter as the Company's new Chief Financial Officer (CFO). Mr. Carter is an experienced ASX-listed company CFO and brings over 20 years of experience in executive roles at various biotech companies. Notably, he was part of the senior management team involved in the USA Initial Public Offering of a dual listed NASDAQ firm. Mr. Carter holds a Bachelor of Financial Administration (UNE), a Master of Applied Finance (Macquarie University) and is a qualified Chartered Accountant. As Actinogen advances the expansion of its clinical development pipeline, Mr. Carter's extensive corporate experience will be a valuable addition to the senior management team.

Strong cash position

Actinogen's cash balance as at 30 September 2020 was A$4.3m, excluding funds received from the placement and research and development (R&D) tax incentive rebate received subsequent to the quarter. Net operating cash outflows for the quarter was A$728,000, mostly related to R&D expenditure and staff directly involved in R&D, and corporate costs. This cash outflow marked a significant decrease over the prior quarter outflow of A$2.3m and reflects the completion of the previous clinical trial program, as flagged in the June 2020 Quarterly Update.

Subsequent to the quarter, Actinogen strengthened its cash position through the successful completion of a A$6.0m placement supported by new investors and existing shareholders, including its largest shareholder BVF Partners. The Company currently has a 1 for 5 Entitlement Offer open to eligible shareholders to raise up to an additional ~A$4.9m. The Offer will close at 5:00pm (AEDT) on Tuesday, 10 November 2020. The Company also received a research and development (R&D) tax incentive rebate of approximately A$2.9m in October 2020 in relation to its R&D spend in the 2020 financial year. Actinogen is now in a strong position to progress both the **XanaMIA and XanaFX** phase II clinical trials.

Listing Rule 4.7C.3

In item 6 of the attached Appendix 4C of the cashflow report for the quarter, payments to Related Parties of approximately A$145,000 is comprised of the salary for the Managing Director and fees paid to the Non-Executive Directors.

Outlook: Multiple upcoming clinical trials

Actinogen is making good progress in the development of Xanamem in the treatment of serious and debilitating conditions with a high unmet medical need. The multiple indications in the portfolio and the upcoming clinical trials present a number of key catalysts in the new-to-medium term. The Company's strengthened senior management team and the additional funds being raised, places the Company in a strong position going forward.

Plans are advancing rapidly for the phase II **XanaMIA** trial, targeting patients with MCI due to AD. Actinogen expects recruitment to commence in 1H CY21, and for the trial to complete within 24 months of commencement. The trial will be funded by the proceeds raised through the current capital raising.

The phase II **XanaFX** trial in FXS patients is also expected to commence in 1H CY21. The study is fully funded and should complete within 12 months of commencement. Additionally, the Company is progressing through the regulatory pathway towards potentially achieving ODD and RPDD designations for Xanamem in FXS.

Regulatory activities are well underway in the lead up to the commencement of both trials, and the Company will provide further updates in due course.

Actinogen is committed to developing Xanamem as a treatment to a range of medical conditions, presenting with a high unmet medical need and significant market potential. The broadening of Actinogen's portfolio with the addition of FXS is a testament to the breadth of treatment opportunities for the Company to explore with Xanamem.

ENDS

Actinogen Medical

Dr. Bill Ketelbey
CEO & Managing Director
P: +61 2 8964 7401
E: bill.ketelbey@actinogen.com.au
@BillKetelbey

Investor Enquiries

Miranda Newnham
Vesparum Capital
P: +61 3 8582 4800
E: actinogen@vesparum.com

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, psychiatric and metabolic diseases associated with chronically elevated cortisol. The company is currently developing its lead compound, Xanamem, as a promising new therapy for Alzheimer's disease, Fragile X syndrome, schizophrenia and diabetes. 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 11β-HSD1 enzyme is particularly highly concentrated in the hippocampus and frontal cortex, areas of the brain impacted by a number of diseases and disorders, including Alzheimer's disease, Fragile X syndrome, schizophrenia, diabetes and other conditions associated with chronically raised cortisol.

The Company's XanaHES Phase I trial exploring the safety and tolerability of Xanamem 20mg once daily in healthy elderly volunteers, confirmed the drug's safety profile with no treatment-related serious adverse events. Additionally, the trial demonstrated that Xanamem produced a statistically significant improvement in cognition over placebo, which, along with other recently generated data, confirms 11β-HSD1 inhibition by Xanamem as a promising potential treatment for cognitive impairment associated with raised cortisol.

The Company plans to initiate Phase II studies of Xanamem in various disease areas in 2021, including MCI due to Alzheimer's disease, and Fragile X syndrome.

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	30 September 2020

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	(76)	(76)
	(b) product manufacturing and operating costs		
	(c) advertising and marketing	(164)	(164)
	(d) leased assets	-	-
	(e) staff costs	(389)	(389)
	(f) administration and corporate costs	(140)	(140)
1.3	Dividends received (see note 3)		
1.4	Interest received	9	9
1.5	Interest and other costs of finance paid	(6)	(6)
1.6	Income taxes paid		
1.7	Government grants and tax incentives – Covid cashflow boost	38	38
1.8	Other	-	-
1.9	**Net cash from / (used in) operating activities**	**(728)**	**(728)**

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		

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 months) $A'000
	(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.	**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 (provide details if material)		
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	5,076	5,076
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(728)	(728)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 months) $A'000
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-
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**	**4,348**	**4,348**

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	813	1,441
5.2	Call deposits	3,500	3,600
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)**	**4,348**	**5,076**

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	145
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)	(728)
8.2	Cash and cash equivalents at quarter end (item 4.6)	4,348
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	4,348
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	5.97

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: 29 October 2020

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.