

ASX ANNOUNCEMENT**December 2020 Quarterly Activity Report & Appendix 4C**

Sydney, 29 January 2020. Actinogen Medical ASX: ACW ('ACW' or 'the Company') today submitted its quarterly activity report and Appendix 4C for the three-month period ended 31 December 2020.

Key highlights:

- **Xanamem™ clinical development plans for the two fully funded trials progressed during the quarter:**
 - XanaMIA phase II trial in patients with Mild Cognitive Impairment 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
- **Two new patent applications filed to strengthen and extend IP portfolio**
- **Ongoing focus on business development activities, including a presentation at Switzer Small and Micro Cap Investor Day**
- **Strong cash position with ~\$12.9m held as at 31 December 2020, including funds received during the quarter from the placement (~\$6.0m), entitlement offer (~\$1.4m) and a R&D tax incentive rebate for FY20 (~\$2.9m)**

Advancing clinical development – planning for multiple clinical trials

Actinogen continued to 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 planning a new Xanamem study in an AD patient population. The 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 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 made significant progress with anxiety, sleep and behavioural problems in Fragile X syndrome (FXS) being added 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. XanaFX, is a double-blind placebo-controlled trial investigating the treatment of Xanamem in ~40 male adolescents with FXS. The trial will be conducted by the Murdoch Children's Research Institute and the Royal Children's Hospital.

During the quarter, Dr. Bill Ketelbey presented an update on Actinogen's clinical development on 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>

New patent applications to strengthen IP portfolio

Actinogen filed two new patent applications for lead drug Xanamem which could extend its patent life protection until 2040. The first application seeks to provide patent protection to a method of treating cognitive decline. This patent is supported by the statistically significant results of the Phase I XanaHES trial, which

suggest that Xanamem meaningfully improves cognition over placebo in cognitively healthy subjects. The second application provides patent protection to a commercial scale-up manufacturing process for Xanamem, which enables direct access to high purity Xanamem through a unique synthesis methodology. This innovation allows Actinogen to leverage its production by effectively manufacturing Xanamem at larger scale quantities in preparation for future commercialisation and clinical trials. Actinogen continues to proactively extend its IP portfolio by seeking patent opportunities and extending patent life protection for Xanamem.

Ongoing business development activities and engagement with investors, commercial and strategic parties

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/>.

In early December, Actinogen CEO and MD Dr. Bill Ketelbey delivered a presentation at the Switzer Small and Micro Cap Virtual Investor Day. His presentation targeted new investors and outlined the key hypotheses and outcomes from Xanamem studies and Actinogen's progress in clinical trials.

The Actinogen team continued to progress with the drafting of 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.

Strong cash position

Actinogen's cash balance as at 31 December 2020 was \$12.95m.

The Company received a research and development (R&D) tax incentive rebate of approximately A\$2.90m in October 2020 in relation to its R&D spend in the 2020 financial year. Net operating cash outflows (excluding the R&D tax incentive rebate) for the quarter was \$1.12m, mostly related to R&D spend of \$0.49m and staff costs of \$0.35m.

Also, during the quarter, Actinogen raised an aggregate of A\$7.36m (before transaction related costs) from the placement and entitlement offer. The oversubscribed placement raised A\$6.00m with support from new investors and existing shareholders, including Actinogen's largest shareholder BVF Partners. The Company also completed a 1 for 5 entitlement offer which raised A\$1.36m from existing shareholders.

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\$0.14m is comprised of the salary for the Managing Director and fees paid to the Non-Executive Directors.

Outlook: Multiple upcoming clinical trials

Actinogen is advancing the development of Xanamem in the treatment of serious and debilitating conditions with a high unmet medical need and significant market potential, with plans for a number of clinical trials. 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.

The strong cash position ensures Actinogen is well placed going forward.

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, 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 11 β -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 11 β -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 11 β -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

14 086 778 476

Quarter ended ("current quarter")

31 December 2020

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers		
1.2 Payments for		
(a) research and development	(492)	(568)
(b) product manufacturing and operating costs		
(c) advertising and marketing		
(d) leased assets	-	-
(e) staff costs	(354)	(743)
(f) administration and corporate costs	(224)	(507)
1.3 Dividends received (see note 3)		
1.4 Interest received	7	16
1.5 Interest and other costs of finance paid	(6)	(12)
1.6 Income taxes paid		
1.7 Government grants and tax incentives	2,896	2,934
1.8 Other (Miscellaneous, GST)	(55)	(55)
1.9 Net cash from / (used in) operating activities	1,772	1,065
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 (6 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)	7,360	7,360
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	(511)	(511)
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)	(21)	(42)
3.10 Net cash from / (used in) financing activities	6,828	6,807

4. Net increase / (decrease) in cash and cash equivalents for the period		
4.1 Cash and cash equivalents at beginning of period	4,348	5,076
4.2 Net cash from / (used in) operating activities (item 1.9 above)	1,772	1,065
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 (6 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	6,828	6,807
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	12,948	12,948

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	10,913	813
5.2	Call deposits	2,000	3,500
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)	12,948	4,348

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	139
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
<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>		

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

7. Financing facilities	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
<i>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.</i>		
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)	1,772
8.2 Cash and cash equivalents at quarter end (item 4.6)	12,948
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	12,948
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	N/A
<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: 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	
<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: 29 January 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.