ASX ANNOUNCEMENT

June 2020 Quarterly Activity Report & Appendix 4C

- **Xanamem™ clinical development plans advancing**
  - **Detailed data modelling and analysis progressed to final stages, with conclusions optimising design parameters for next series of clinical studies, including dosing and patient characteristics**
  - **Preparation for a clinical trial in Mild Cognitive Impairment due to Alzheimer's disease, building on the compelling XanaHES clinical trial results with 20mg Xanamem daily**
- **Ongoing focus on business development activities, including presentation of key data underpinning Xanamem development at the AD/PD and BIO Digital conferences**
- **Solid cash runway underpinned by $5.1m cash held as at 30 June 2020 and a FY20 R&D tax rebate expected in 2H CY20**

Sydney, 29 July 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 June 2020.

Advancing clinical development plans for multiple trials

During the quarter, Actinogen continued to advance and optimise clinical development plans for its lead drug, Xanamem. The Phase I Target Occupancy study demonstrates that the drug works as designed and has been shown to bind to the target 11β-HSD1 enzyme, in the areas of brain considered responsible for much of the cognitive impairment associated with increased cortisol across numerous disease states. The study demonstrated that doses of Xanamem between 5mg and 30mg, effectively block the neuronal 11β-HSD1 enzyme in the brain. While finalising the study has been delayed by Covid-19, 31 out of 36 patients have completed, providing valuable data to include in the overall Xanamem data modelling underway.

Following the XanADu study that dosed Xanamem at 10mg daily, Actinogen completed the Phase 1 XanaHES study, trialling a higher dose of Xanamem at 20mg daily in a healthy ageing population. The Company was delighted with the breakthrough efficacy results from this study demonstrating that 20mg Xanamem daily produced a statistically significant improvement in cognition in those elderly patients, and that 20mg Xanamem daily was appropriately safe in this population and effectively inhibited cortisol production.

The detailed data modelling and analysis of the substantial dataset generated from numerous Xanamem studies including XanADu, XanaHES and the PET Target Occupancy study, is now in the final stages, with the expected output optimising study parameters for the next set of clinical studies. Additionally, global Alzheimer's disease research and development is rapidly evolving, with many biomarkers now measurable in the blood. Actinogen will use this breakthrough technology to optimise patient selection and strengthen the efficacy evaluation in the next set of Xanamem clinical trials.

Leveraging the substantial dataset and success of the XanaHES study, Actinogen is now planning to trial 20mg Xanamem daily in patients at the very early stages of cognitive decline due to Alzheimer's disease. This condition is Mild Cognitive Impairment (MCI) due to Alzheimer's disease, and the study will link the positive XanaHES trial results with an Alzheimer's disease patient population.

In parallel, Actinogen is targeting a range of other disease areas, including cognitive impairment associated with both schizophrenia and diabetes, and assessing additional potential opportunities, as they arise.

Some disruptions have been experienced as a result of Covid-19 global restrictions during the quarter. There have been minor delays to Actinogen's ongoing pre-clinical toxicology studies and the PET Target Occupancy study, however work on these studies had resumed by the end of the quarter. Due to the re-emergence of Covid-19 in Victoria, the enrolment into the Target Occupancy study has since been suspended again.

Ongoing business development activities and engagement with commercial and strategic parties

During the quarter, Professor Craig Ritchie, Chair of Actinogen's Xanamem Clinical Advisory Board presented an update of Actinogen's progress in developing Xanamem at the Advancement in Alzheimer's and Parkinson's Therapies Focus Meeting (AAT-AD/PD). This international scientific congress reviews the latest breakthroughs in drug development, translational R&D, early diagnosis, and clinical trials in Alzheimer's and Parkinson's disease with an audience of leading academic and biopharma industry experts. This year the meeting was held as an entirely virtual event, and Actinogen is pleased to have contributed its data produced on Xanamem to this body of knowledge. The recorded presentation can be found on Actinogen's website here.

In early June, Dr. Bill Ketelbey presented at, and participated in the BIO Digital event, which provided an opportunity for Actinogen to update major pharmaceutical companies and potential partners on the substantial dataset generated on Xanamem and on its future development plans. In addition, a literature review covering the potential of the 11ß-HSD1 enzyme was accepted for publication in the peer-reviewed journal, *Metabolism: Clinical and Experimental.* The review by Dr. Sarah Gregory, supports the ongoing clinical development of Xanamem across numerous indications and focusses on gaining more understanding into the complex relationship between 11ß-HSD1 enzyme and disease pathology.

Subsequent to the quarter end, Professor Craig Ritchie presented a poster on behalf of Actinogen at the Alzheimer's Association International Conference (AAIC). Additionally, in July, Dr. 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. Bill Ketelbey also presented at Finance News Network (FNN) on Tuesday 28 July, providing an update on Actinogen to shareholders and the investment community. The recorded FNN presentation will be on our website https://actinogen.com.au/media-center/#in-the-news.

Strong cash position

Actinogen's cash balance as at 30 June 2020 was $5.1m, with net operating cash outflows for the quarter of $2.3m, which was up from $1.1m for the previous quarter. The increased cash outflow in the June quarter related to increased research and development expenditure of $726k and a reduction in government grants and tax incentives received of $480k. This cash outflow is not reflective of future expected spend however, as all ongoing trials are closing off, and R&D expenditure will be limited during preparation for the expected initiation of the planned Phase 2 clinical trials.

Further, the Company expects a R&D tax rebate of approximately $2.9m in 2H CY20, in relation to its R&D spend in FY20. Actinogen also continues to submit numerous grant applications to support the upcoming clinical trials and is exploring additional opportunities for non-dilutive trial funding.

Listing Rule 4.7C.3

In item 6 of the attached Appendix 4C of the cash flow report for the quarter, payments to Related Parties of approximately $142,000 is comprised of the salary paid to the Managing Director and fees paid to the Non-Executive Directors.

Outlook: Multiple upcoming clinical trials

As the unprecedented global crisis resulting from the Covid-19 outbreak continues to evolve, Actinogen is emerging with limited disruption through careful and proactive management and is in a strong position to commence new clinical trials, as soon as practical.

Strong progress continues to be made with planning for the clinical trial in MCI due to Alzheimer's disease, and the Company looks forwards to providing further updates in due course. The broadening portfolio to target additional indications, including cognitive impairment in schizophrenia and diabetes and potentially other conditions, highlights the breadth of treatment and development opportunities for Actinogen to explore with Xanamem.

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 cognitive impairment associated with chronic neurological, psychiatric, and metabolic diseases. The company is currently developing its lead compound Xanamem as a promising new therapy for Alzheimer's disease, and cognitive impairment associated with schizophrenia, diabetes, and other disorders. The cognitive dysfunction 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 sets it apart from currently available therapies. It 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 particular behavioural symptoms. The 11β-HSD1 enzyme is highly concentrated in the hippocampus and frontal cortex, the areas of the brain associated with cognitive impairment in a number of diseases/disorders, including Alzheimer's disease, schizophrenia, diabetes and other conditions associated with cognitive impairment.

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 strong safety profile with no treatment-related serious adverse events. Additionally, the trial demonstrated that Xanamem produced a statistically significant improvement in cognition, which, along with other recently generated data, confirms 11β-HSD1 inhibition by Xanamem as a promising potential treatment for cognitive impairment and other symptoms associated with raised cortisol.

The Company plans to initiate Phase II studies of Xanamem in various disease areas in 2020/21, including MCI due to Alzheimer's disease.

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) 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 June 2020

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	(2,198)	(7,871)
	(b) product manufacturing and operating costs		
	(c) advertising and marketing	(165)	(728)
	(d) leased assets	-	(14)
	(e) staff costs	(32)	(130)
	(f) administration and corporate costs	(92)	(421)
1.3	Dividends received (see note 3)		
1.4	Interest received	17	94
1.5	Interest and other costs of finance paid	(1)	(6)
1.6	Income taxes paid		
1.7	Government grants and tax incentives	174	5,459
1.8	Other (Supplier repayment of overcharged invoices)	-	684
1.9	**Net cash from / (used in) operating activities**	**(2,297)**	**(2,933)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities		
	(b) businesses		
	(c) property, plant and equipment	(4)	(23)
	(d) investments		
	(e) intellectual property		

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 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**	**(4)**	**(23)**

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	-	360
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**	**-**	**360**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	7,377	7,672
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,297)	(2,933)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(4)	(23)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	360
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of period**	**5,076**	**5,076**

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	1,476	3,278
5.2	Call deposits	3,600	4,100
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**5,076**	**7,378**

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	142
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)	(2,297)
8.2	Cash and cash equivalents at quarter end (item 4.6)	5,076
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	5,076
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	2.21

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 July 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.