ASX ANNOUNCEMENT

September 2019 Quarterly Update

- **Breakthrough efficacy results from XanaHES Phase I study:**
  - **Xanamem 20mg daily demonstrated statistically significant cognitive improvement in healthy elderly subjects**
  - **Results mark the first time Xanamem™ has demonstrated such a clear and statistically significant cognitive improvement in human trials**
  - **Results reinforce the cortisol hypothesis and the science underpinning Xanamem's development**
- **Ongoing clinical trial update:**
  - **Target Occupancy studies**
  - **Pre-clinical toxicology studies**
- **R&D Rebate expected during December 2019 quarter**
- **Clarity on Xanamem's efficacy and safety through the expanding dataset will shape Actinogen's future clinical development strategy, which the Company looks forward to outlining in the near term**

Sydney 24 October 2019: Actinogen Medical ASX: ACW ('ACW' or 'the Company') today submitted its Appendix 4C and quarterly update report for the three month period ended 30 September 2019.

XanaHES Phase I Clinical Trial – Statistically significant efficacy results announced

On October 1, the Company announced impressive and positive efficacy and safety results from XanaHES, its Phase I clinical trial designed to assess the safety of 20mg Xanamem daily in healthy elderly subjects. Importantly, this trial included a number of cognition assessments which evaluated the cognitive efficacy of 20mg Xanamem daily using the Cogstate Cognitive Test Battery across six domains.

The trial demonstrated a statistically significant improvement in three of the six cognitive domains – a marked effect size that was seen after only 4 weeks and that was sustained for the full 12 weeks of treatment. Additionally Xanamem 20mg daily produced a statistically significantly reduction in serum cortisol levels among trial participants and exhibited a good safety profile with no treatment-related serious adverse events reported.

The Company views these results as a major breakthrough in the development of Xanamem given it marks the first time Xanamem has demonstrated such a clear and statistically significant cognitive improvement in human trials. The results endorse and reinforce the 'cortisol hypothesis' and the science that underpins the development of Xanamem.

As reported to the market in May, the XanADu trial in mild Alzheimer's patients showed that while Xanamem 10mg daily was safe and impacted cortisol production, it did not demonstrate an improvement in cognition in the Alzheimer's population enrolled into the study. The latest XanaHES results provide the Company with clear evidence that the higher dose of 20mg Xanamem daily has the potential to be a more therapeutically effective dose, and these XanaHES results help to clarify the outcomes of the XanADu study.

The Company continues to build a much clearer picture of Xanamem's efficacy and safety, and its potential in a number of disease areas, as it reviews the data from XanaHES and other ongoing studies. The totality of these study results will help shape Actinogen's clinical development strategy for Xanamem, which the Company looks forward to outlining over the remainder of 2019 and into next year.

Ongoing Trial Updates:

During the September quarter, Actinogen continued to enhance Xanamems's dataset through the ongoing Xanamem studies.

Target Occupancy Studies: Phase 1 PET study and homogenate binding studies

The Target Occupancy studies are designed to measure the effect of different Xanamem doses on inhibiting the 11β-HSD1 enzyme in the brain, and will help confirm the optimum dosing regimen for Xanamem in future clinical trials. These studies include the Phase 1 PET and in-vitro homogenate binding studies.

Preliminary results from the Phase 1 PET study has shown that 10-30mg Xanamem significantly binds to the 11β-HSD1 enzyme in the brain, with between 50 to 85 per cent occupancy, depending on the brain region, Xanamem dosage and study subjects. Further results are expected in the final quarter of CY2019.

The Target Occupancy homogenate binding studies are in-vitro studies designed to confirm and enhance the Phase 1 PET data. Results from these studies are also expected before the end of the year.

Pre-clinical toxicology studies

As reported to the market in July, prior to the commencement of longer-term clinical studies, regulatory authorities require long-term toxicology studies in two non-primate species – rodents for six months and dogs for nine months.

The studies will allow Actinogen to conduct future clinical studies beyond 12 weeks and are currently ongoing. The Company is pleased to report there have been no substantial safety issues reported in the toxicology studies to date, and expects that human trials employing durations of treatment beyond 12 weeks will be approved by the regulators in the future.

R&D Rebate expected

The Company expects to receive approximately $4.6m in FY2019 R&D Tax rebates in the December 2019 quarter, with a further FY2019 rebate of up to $0.65m expected thereafter.

Outlook

Actinogen CEO and Managing Director, Dr Bill Ketelbey noted the quarter was particularly productive and that the Company was delighted with the positive XanaHES results released earlier this month.

"The XanaHES results are the first time Xanamem has shown such a clear and statistically significant cognitive improvement in human trials. These results are hugely significant in the development of Xanamem for the treatment of Alzheimer's disease, and other conditions associated with cognitive impairment," said Dr Ketelbey.

"In the coming months, we look forward to informing the market on our next series of studies planned for the ongoing clinical development of Xanamem."

ENDS

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About Actinogen Medical

Actinogen Medical (ASX: ACW) is an ASX-listed biotechnology company focused on innovative approaches to treating cognitive decline that occurs in chronic neurological and metabolic diseases. Actinogen Medical is developing its lead compound Xanamem, as a promising new therapy for Alzheimer's disease, a condition with multibillion-dollar market potential and material human impact. In the US alone, the cost of managing Alzheimer's disease is estimated to be US$250bn and is projected to increase to US$2tn by 2050, outstripping the treatment costs of all other diseases. Alzheimer's disease is now the leading cause of death in the UK and second only to ischaemic heart disease in Australia. In addition, Actinogen is currently planning an expanded clinical development program for Xanamem in cognitive impairment in mood disorders and schizophrenia. In the US alone, the collective economic costs of mood disorders and schizophrenia are estimated to exceed $550bn, with the burden increasing every year. The cognitive dysfunction associated with these conditions is significantly debilitating for affected patients, with a substantial unmet medical need for novel, improved treatments.

About Xanamem™

Xanamem's novel mechanism of action sets it apart from other Alzheimer's treatments. It works by blocking the excess production of cortisol - the stress hormone – through the inhibition of the 11β-HSD1 enzyme in the brain. There is a strong association between chronic stress and excess cortisol that leads to changes in the brain affecting memory. The 11β-HSD1 enzyme is highly concentrated in the hippocampus and frontal cortex, the areas of the brain associated with cognitive impairment in neurological diseases, including Alzheimer's disease, mood disorders and schizophrenia.

About XanADu

XanADu is a Phase II double-blind, 12-week, randomised, placebo-controlled study to assess the safety, tolerability and efficacy of Xanamem 10mg daily in subjects with mild dementia due to Alzheimer's disease. XanADu has fully enrolled 186 patients from 25 research sites across Australia, the UK and the USA. The trial is registered on www.clinicaltrials.gov with the identifier: NCT02727699, where more details on the trial can be found, including the study design, patient eligibility criteria and the locations of the study sites.

About XanaHES

XanaHES is a Phase I, randomised, single blinded, central reader blinded, placebo-controlled, dose escalation study to assess the safety and tolerability of Xanamem™ 20mg & 30mg once daily in healthy elderly volunteers. Changes in cognitive performance from baseline to end-of-treatment are measured as an exploratory efficacy outcome.

Actinogen Medical encourages all current investors to go paperless by registering their details with the designated registry service provider, Link Market Services.

+Rule 4.7B

Appendix 4C

Quarterly report for entities subject to Listing Rule 4.7B

Introduced 31/03/00 Amended 30/09/01, 24/10/05, 17/12/10, 01/09/16

Name of entity

ACTINOGEN MEDICAL LIMITED

ABN	**Quarter ended ("current quarter")**
14 086 778 476	30 September 2019

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	(1,983)	(1,983)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(229)	(229)
	(d) leased assets	-	-
	(e) staff costs	(33)	(33)
	(f) administration and corporate costs	(143)	(143)
1.3	Dividends received	-	-
1.4	Interest received	38	38
1.5	Interest and other costs of finance paid	(2)	(2)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	28	28
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(2,324)**	**(2,324)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) property, plant and equipment	-	-
	(b) businesses (see item 10)	-	-
	(c) investments	-	-

Consolidated statement of cash flows		**Current quarter** $A'000	**Year to date (3 months)** $A'000
	(d) intellectual property	-	-
	(e) other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(a) property, plant and equipment	-	-
	(b) businesses (see item 10)	-	-
	(c) investments	-	-
	(d) intellectual property	-	-
	(e) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received	-	-
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 shares	-	-
3.2	Proceeds from issue of convertible notes	-	-
3.3	Proceeds from exercise of share options	-	-
3.4	Transaction costs related to issues of shares, convertible notes or options	-	-
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (repayment of loan shares by former Directors/Employee)	-	-
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 quarter/year to date	7,672	7,672
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,324)	(2,324)
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)	-	-

Consolidated statement of cash flows		**Current quarter** **$A'000**	**Year to date (3 months)** **$A'000**
4.5	Effect of movement in exchange rates on cash held	(1)	(1)
4.6	**Cash and cash equivalents at end of quarter**	**5,347**	**5,347**

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	1,247	1,572
5.2	Call deposits	4,100	6,100
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)**	**5,347**	**7,672**

6.	**Payments to directors of the entity and their associates**	**Current quarter $A'000**
6.1	Aggregate amount of payments to these parties included in item 1.2	135
6.2	Aggregate amount of cash flow from loans to these parties included in item 2.3	-

6.3 Include below any explanation necessary to understand the transactions included in items 6.1 and 6.2

Directors' fees, salaries including superannuation benefits and professional consultancy fees. All payments are on normal commercial terms.

7.	**Payments to related entities of the entity and their associates**	**Current quarter $A'000**
7.1	Aggregate amount of payments to these parties included in item 1.2	-
7.2	Aggregate amount of cash flow from loans to these parties included in item 2.3	-

7.3 Include below any explanation necessary to understand the transactions included in items 7.1 and 7.2

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8.	**Financing facilities available** *Add notes as necessary for an understanding of the position*	**Total facility amount at quarter end $A'000**	**Amount drawn at quarter end $A'000**
8.1	Loan facilities	-	-
8.2	Credit standby arrangements	-	-
8.3	Other (please specify)	-	-

8.4 Include below a description of each facility above, including the lender, interest rate and whether it is secured or unsecured. If any additional facilities have been entered into or are proposed to be entered into after quarter end, include details of those facilities as well.

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9.	**Estimated cash outflows for next quarter**	**$A'000**
9.1	Research and development	3,096
9.2	Product manufacturing and operating costs	-
9.3	Advertising and marketing	165
9.4	Leased assets	-
9.5	Staff costs	31
9.6	Administration and corporate costs	121
9.7	Other	-
9.8	**Total estimated cash outflows**	**3,413**

Note: The Company expects to receive approximately $4.6m in FY2019 R&D Tax rebates in the December 2019 quarter, with a further FY2019 rebate of up to $0.65m expected thereafter.

10.	**Acquisitions and disposals of business entities (items 2.1(b) and 2.2(b) above)**	**Acquisitions**	**Disposals**
10.1	Name of entity	-	-
10.2	Place of incorporation or registration	-	-
10.3	Consideration for acquisition or disposal	-	-
10.4	Total net assets	-	-
10.5	Nature of business	-	-

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.

Sign here: ..... Date: 24 October 2019
Company Secretary

Print name: Peter Webse

Notes

1. The quarterly report provides a basis for informing the market how the entity's activities have been financed for the past quarter and the effect on its cash position. An entity that wishes to disclose additional information is encouraged to do so, in a note or notes included in or attached to this report.

2. If this quarterly 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 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.