

ASX ANNOUNCEMENT

December 2018 Quarterly Update

- Significant milestone achieved for XanADu, with the final patient, of 186, enrolled into trial
- Continued engagement with biotech investors and potential pharma partners
- Interest in cortisol/Alzheimer's hypothesis continues to build with supportive research
- Retirement of Dr Jason Loveridge as a Non-Executive Director

Sydney 29 January 2019: Actinogen Medical ASX: ACW ('ACW' or 'the Company') has today submitted its Appendix 4C for the three-month period ended 31 December 2018 and is pleased to release this Quarterly Update Report.

Operational Update

Major milestone achieved - final patient enrolled in landmark XanADu trial

In November, Actinogen Medical announced enrolment of the final patient into XanaADu, the landmark Phase II clinical trial of Xanamem in the treatment of patients with mild Alzheimer's disease. A total of 186 patients were enrolled into the trial, surpassing the initial target of 174. Enrolment was also achieved ahead of the target date.

The XanADu results will be pivotal in the Company's development as the study is designed to provide an indication of safety and efficacy of Xanamem in the treatment of Alzheimer's disease, and place the Company an important step closer to bringing to market a new and novel treatment for this disease.

Actinogen Medical remains on track to report out results from the XanADu trial during the second quarter 2019, as previously announced.

Corporate Update

Continued engagement with biotech investors and potential pharma partners

During the period, Actinogen Medical presented at numerous investor, biotech, and Alzheimer's research conferences, including:

- AC4R (Sydney, Oct 12)
- Australian Microcap Investment Conference (Melbourne, Oct 18)
- AusBiotech Invest and Partnering Conference (Melbourne, Oct 30)
- Clinical Trials on Alzheimer's Disease - CTAD (Barcelona, Oct 24-27)

Dr Bill Ketelbey also presented at the 2nd Annual SACHS Neuroscience Innovation Forum during JPM Week (6th – 10th January) in San Francisco.

The SACHS Neuroscience Innovation Forum brings together biotech companies focused on central nervous system conditions, with pharma partners and investors.

Additionally, Actinogen Medical participated in multiple partnering and investor meetings during the JPM week, updating the pharma industry and major global investors interested in neuroscience on the Company's

progress to date with the development of Xanamem, including XanADu in Alzheimer's disease, and the initiation of nine additional Xanamem studies over the past 6 months.

Interest in cortisol thesis continues to build with supportive research

In November, Actinogen Medical was pleased to highlight a recent study in *Neurology*, the most highly regarded global peer-reviewed neurology journal, demonstrating an association between higher serum (blood) cortisol, impaired cognitive performance, and decreased brain volume.

Titled '[*Circulating cortisol and cognitive and structural brain measures*](#)' (Echouffo-Tcheugui et al., 2018), this study builds on an increasing body of evidence linking persistently raised cortisol levels with cognitive impairment and Alzheimer's disease.

This emergent data provides further support for the premise underpinning the development of Xanamem, which has been specifically designed to inhibit the excess production of cortisol in the brain, and particularly in the areas of the brain most impacted by Alzheimer's disease.

Retirement of Dr Jason Loveridge as a Non-Executive Director

In November, Actinogen Medical advised that Dr Jason Loveridge had retired as a Non-Executive Director of the Company. Dr Loveridge had been a Non-Executive Director since the establishment of Actinogen Medical in 2014 and was instrumental in initially identifying what are now Actinogen's technology and compounds as a potential licensing opportunity, whilst also providing valuable guidance in their subsequent development. Actinogen Medical thanked Dr Loveridge for his valued input, and a decision on his replacement will be made by the Board in due course.

Outlook

Commenting on progress made during the period, CEO Dr Bill Ketelbey said: "We have had another extremely productive quarter, achieving a significant milestone with the enrolment of the final patient into the XanADu trial. Our team was delighted to enrol a total of 186 patients, which exceeded the original patient target of 174 patients. This is a testament to the quality of execution across multiple aspects of this trial, and we eagerly await results from this landmark study which will be announced in the second quarter of 2019."

"In addition to progress made with the XanADu trial during the period, we were also very pleased with the engagement of potential pharma partners and investors who we met with over the quarter, including in San Francisco during JPM Week. The JPM week attracts leading global biopharmaceutical industry and specialist biotech investors and was an excellent opportunity to showcase the Company's progress with the development of Xanamem. In addition to our positive progress to date, emerging research around the cortisol hypothesis has been very supportive in driving further engagement and interest from key stakeholders in the association between cortisol and Alzheimer's disease, and the potential for Xanamem as a treatment for this disease."

ENDS

Actinogen Medical

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About Actinogen Medical

Actinogen Medical (ASX: ACW) is an ASX-listed biotech company focused on innovative approaches to treating cognitive decline that occurs in chronic neurodegenerative and metabolic diseases. Actinogen Medical is developing its lead compound Xanamem, as a promising new therapy for Alzheimer's disease, a condition with a multibillion-dollar market potential. In the US alone, the cost of managing Alzheimer's disease is estimated to be US\$250bn and is set 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

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. This enzyme is highly concentrated in the hippocampus and frontal cortex, the areas of the brain most affected by Alzheimer's disease. There is a strong association between chronic stress and excess cortisol that leads to changes in the brain affecting memory, and to the development of amyloid plaques and neural death – all hallmarks of Alzheimer's disease.

About XanADu

XanADu is a Phase II double-blind, 12-week, randomised, placebo-controlled study to assess the safety, tolerability and efficacy of Xanamem 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. Results are expected in Q2 2019. 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.

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 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

14 086 778 476

Quarter ended ("current quarter")

31 December 2018

Consolidated statement of cash flows	Current quarter	Year to date
	\$A'000	(6 months)
		\$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers		
1.2 Payments for		
(a) research and development	(4,087)	(5,126)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(207)	(324)
(d) leased assets	-	-
(e) staff costs	(34)	(89)
(f) administration and corporate costs	(87)	(255)
1.3 Dividends received	-	-
1.4 Interest received	24	59
1.5 Interest and other costs of finance paid	(2)	(2)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	3,178	3,178
1.8 Other (provide details if material)	-	-
1.9 Net cash from / (used in) operating activities	(1,215)	(2,559)
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	Year to date (6 months)
	\$A'000	\$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	-	7,156
3.2 Proceeds from issue of convertible notes	-	-
3.3 Proceeds from exercise of share options	555	690
3.4 Transaction costs related to issues of shares, convertible notes or options	-	(310)
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)	520	520
3.10 Net cash from / (used in) financing activities	1,075	8,056
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	15,641	10,004
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(1,215)	(2,559)
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)	1,075	8,056

Consolidated statement of cash flows		Current quarter	Year to date (6 months)
		\$A'000	\$A'000
4.5	Effect of movement in exchange rates on cash held	2	2
4.6	Cash and cash equivalents at end of quarter	15,503	15,503

5. Reconciliation of cash and cash equivalents	Current quarter	Previous quarter
at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	\$A'000	\$A'000
5.1	Bank balances	9,830
5.2	Call deposits	174
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)	10,004

6. Payments to directors of the entity and their associates

- | | Current quarter |
|-----|------------------------|
| | \$A'000 |
| 6.1 | 130 |
| 6.2 | - |
| 6.3 | |

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 | - |
| 7.2 | - |
| 7.3 | |

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8. Financing facilities available <i>Add notes as necessary for an understanding of the position</i>	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	3,956
9.2 Product manufacturing and operating costs	-
9.3 Advertising and marketing	152
9.4 Leased assets	-
9.5 Staff costs	31
9.6 Administration and corporate costs	94
9.7 Other	-
9.8 Total estimated cash outflows	4,233

Note: The Company received an R&D rebate of \$3.15 million in early October 2018.

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:



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Company Secretary

Date: 29 January 2019

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.