

**ASX ANNOUNCEMENT****September 2018 Quarterly Update**

- **Expanded Xanamem Clinical Development Program announced and underway**
- **DSMB reaffirms recommendation to continue XanADu trial without modification following second interim review**
- **Major milestone achieved with XanADu recruitment target of 174 patients achieved. Study now closed to new patients.**
- **R&D Tax Incentive rebate of \$3.15m received, further strengthening capital position**
- **Ongoing engagement with biotech investors and Alzheimer's research community**

**Sydney 31 October 2018: Actinogen Medical ASX: ACW ('ACW' or 'the Company')** has today submitted its Appendix 4C for the three-month period ended 30 September 2018 and is pleased to release this Quarterly Update Report.

**Operational Update****Expanded Xanamem Clinical Development Program**

Following a successful \$16.5m capital raise in July, Actinogen Medical announced additional studies for Xanamem to expand its clinical data set and to further value-add to prospective partnering discussions. The Company's expanded development program includes:

*A target occupancy study* to establish the effect different doses of Xanamem has on inhibiting the 11B-HSD1 enzyme in the human brain. Initial work with this study is already underway, with results anticipated in Q2 2019, in line with the expected top-line results for XanADu.

*A higher dose safety study* to expand the safety data-set for Xanamem and allow for higher doses of the drug to be used, if required, including in non-Alzheimer's applications. This human study is expected to initiate in Q4 2018.

*Additional safety toxicology studies* to allow for longer treatment periods, as required by global regulatory authorities in the development of any drug. These studies are also expected to initiate in Q4 2018.

Actinogen Medical is also evaluating a number of promising new clinical indications for Xanamem to expand its potential use beyond Alzheimer's. These include conditions associated with cortisol induced cognitive impairment, such as diabetes, depression, Parkinson's disease and schizophrenia as well as post-traumatic stress disorder (PTSD) and post-myocardial infarction. The Company expects to complete an ongoing review of all potential indications within the next few months.

**R&D Tax Rebate Received**

In early October, Actinogen Medical received an ATO R&D Tax Incentive rebate of \$3.15 million for the 2017/2018 financial year, further strengthening the Company's capital position. The Company has approximately \$18.65m in cash and cash equivalents following receipt of these funds.

## **XanADu safety reaffirmed as trial continues without modification**

In August, Actinogen Medical announced that the XanADu Data Safety Monitoring Board (DSMB) had reaffirmed that the trial should continue without modification, following a second scheduled interim data review. The DSMB is responsible for overseeing the safety of the trial, and this recent review involved evaluation of safety data from 125 patients. A third and final review of XanADu by the DSMB is expected before the end of 2018.

## **XanADu achieves major enrolment milestone**

In October, Actinogen Medical was delighted to announce that XanADu, the Phase II clinical trial of Xanamem in the treatment of Alzheimer's disease, had achieved enrolment of the planned 174 patients.

While patient recruitment has now closed, the study will surpass the planned 174 patients as the final few patients undergo evaluation for trial eligibility. The Company looks forward to confirming the final patient enrolment number over the next few weeks. XanADu has generated high engagement from study sites and research teams involved in the trial and this rapid completion of patient recruitment was achieved in part through the opening of 5 new XanADu study sites during the quarter.

Once the last patient has been enrolled into XanADu, the countdown to study completion and announcement of the top-line results will commence. Importantly the Company remains on track to announce the top-line results for XanADu in Q2 CY19.

## **Corporate Update**

### **Ongoing engagement with biotech investors and Alzheimer's research community**

Throughout the period, Actinogen Medical participated in a number of conferences to present updates on the Company, and the ongoing development of Xanamem. These updates included the latest progress and milestones achieved, particularly with regard to the Phase II XanADu trial. The conferences attended included:

- Healthcare Investment Day (Singapore, Sept 12)
- Finance News Network Investor Conference (Sydney, Sept 18)
- Australian Microcap Investment Conference (Melbourne, Oct 18)
- AusBiotech Invest and Partnering Conference (Melbourne, Oct 30)
- Clinical Trials on Alzheimer's Disease (Barcelona, Oct 24<sup>th</sup>-27<sup>th</sup>)

In addition to the investor conferences, Actinogen Medical participated in the Clinical Trials on Alzheimer's Disease (CTAD) conference in Barcelona, from 24<sup>th</sup> – 27<sup>th</sup> of October. CTAD is one of the most prestigious global conferences focused on Alzheimer's disease and development of the next generation of treatments.

At the CTAD conference, Professor Craig Ritchie, Chair of the Xanamem Clinical Advisory Board, presented an update on the XanADu trial and Actinogen's new and ongoing clinical studies, including the potential new indications for Xanamem.

Additionally, Sarah Gregory PhD from the University of Edinburgh, presented a scientific poster, outlining her preliminary work in evaluating the role of cortisol in conditions that have potential for treatment with 11 $\beta$ -HSD1 inhibitors, like Xanamem. This research will assist Actinogen in identifying new potential indications to pursue as part of its expanded Xanamem clinical development program.

## Outlook

Commenting on progress made during the period, CEO Dr Bill Ketelbey said: “We have had a particularly productive quarter, with an updated Xanamem development program announced and initiated, a second positive DSMB safety review of XanADu, and most importantly, the accelerated recruitment of patients into the XanADu trial resulting in the achievement of the planned enrolment target for the study ahead of schedule. We anticipate more than the planned 174 patients to be finally enrolled, with the final trial patient number to be announced in November”.

“I would like to thank our team and the study site research staff involved in the XanADu trial, for their extraordinary work during the period to achieve this major milestone ahead of target. In particular I want to thank all the participating patients and their families and carers for their commitment to the study and to the ongoing search for new effective therapies to treat this awful disease”.

“The exceptional engagement and commitment by everyone to the XanADu trial has allowed us to achieve this key milestone ahead of schedule, and we look forward to commencing the countdown to top-line results in 2019 following last patient enrolment which will be announced over the coming weeks”.

## ENDS

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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, is enrolling 174 patients at 25 research sites across Australia, the UK and the USA. Enrolment is expected to complete in Q4 2018, with top-line results expected in Q2 2019. The trial is registered on [www.clinicaltrials.gov](http://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")**

30 September 2018

<b>Consolidated statement of cash flows</b>	<b>Current quarter</b>	<b>Year to date</b>
	<b>\$A'000</b>	<b>(3 months)</b>
		<b>\$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers		
1.2 Payments for		
(a) research and development	(1,039)	(1,039)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(117)	(117)
(d) leased assets	-	-
(e) staff costs	(55)	(55)
(f) administration and corporate costs	(168)	(168)
1.3 Dividends received	-	-
1.4 Interest received	35	35
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	-
1.8 Other (provide details if material)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(1,344)</b>	<b>(1,344)</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire:		
(a) property, plant and equipment	-	-
(b) businesses (see item 10)	-	-
(c) investments	-	-

<b>Consolidated statement of cash flows</b>	<b>Current quarter</b>	<b>Year to date (3 months)</b>
	<b>\$A'000</b>	<b>\$A'000</b>
(d) intellectual property	-	-
(e) other non-current assets	-	-
<b>2.2 Proceeds from disposal of:</b>		
(a) property, plant and equipment	-	-
(b) businesses (see item 10)	-	-
(c) investments	-	-
(d) intellectual property	-	-
(e) other non-current assets	-	-
<b>2.3 Cash flows from loans to other entities</b>	-	-
<b>2.4 Dividends received</b>	-	-
<b>2.5 Other (provide details if material)</b>	-	-
<b>2.6 Net cash from / (used in) investing activities</b>	-	-
<b>3. Cash flows from financing activities</b>		
3.1 Proceeds from issues of shares	7,291	7,291
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	(310)	(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 (provide details if material)	-	-
<b>3.10 Net cash from / (used in) financing activities</b>	<b>6,981</b>	<b>6,981</b>
<b>4. Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1 Cash and cash equivalents at beginning of quarter/year to date	10,004	10,004
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(1,344)	(1,344)
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)	6,981	6,981

<b>Consolidated statement of cash flows</b>		<b>Current quarter</b>	<b>Year to date (3 months)</b>
		<b>\$A'000</b>	<b>\$A'000</b>
4.5	Effect of movement in exchange rates on cash held	-	-
<b>4.6</b>	<b>Cash and cash equivalents at end of quarter</b>	<b>15,641</b>	<b>15,641</b>

<b>5. Reconciliation of cash and cash equivalents</b>	<b>Current quarter</b>	<b>Previous quarter</b>	
at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	<b>\$A'000</b>	<b>\$A'000</b>	
5.1	Bank balances	15,539	9,830
5.2	Call deposits	102	174
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>15,641</b>	<b>10,004</b>

**6. Payments to directors of the entity and their associates**

- |     | <b>Current quarter</b>                                                                               |     |
|-----|------------------------------------------------------------------------------------------------------|-----|
|     | <b>\$A'000</b>                                                                                       |     |
| 6.1 | Aggregate amount of payments to these parties included in item 1.2                                   | 130 |
| 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**

- |     | <b>Current quarter</b>                                                                               |   |
|-----|------------------------------------------------------------------------------------------------------|---|
|     | <b>\$A'000</b>                                                                                       |   |
| 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. <b>Financing facilities available</b> <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. <b>Estimated cash outflows for next quarter</b>	\$A'000
9.1 Research and development	3,565
9.2 Product manufacturing and operating costs	-
9.3 Advertising and marketing	122
9.4 Leased assets	-
9.5 Staff costs	31
9.6 Administration and corporate costs	104
9.7 Other	-
<b>9.8 Total estimated cash outflows</b>	<b>3,822</b>

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

10. <b>Acquisitions and disposals of business entities (items 2.1(b) and 2.2(b) above)</b>	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: 31 October 2018

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.