

## June quarterly update

- Significant milestones achieved with Actinogen's Alzheimer's disease trial, with the successful treatment of the first Australian and US patients
- Represents a landmark in the global search for a new effective treatment for Alzheimer's disease and reinforces Australia's role at the forefront of Alzheimer's research.
- Additional trial sites in Australia, the US and the UK are expected to soon commence enrolling patients, with the final patient planned to be enrolled by Q4 2018.
- Cash at 30<sup>th</sup> June 2017 of \$3.989 million.

**Sydney, 26 July 2017: Actinogen Medical (ASX: ACW)** is pleased to provide a summary of its progress over the quarter ended 30 June 2017.

### **Clinical development progress**

#### *Commencement of XanADu trial*

Actinogen achieved a critical milestone during the quarter with the successful enrolment of the first patients in XanADu, its Phase II clinical trial of Xanamem™ in Alzheimer's disease.

In mid-May, Actinogen enrolled its first Australian patient and the first patient globally into XanADu. This significant achievement followed more than a decade of research undertaken by Edinburgh University in Scotland and Actinogen Medical in Australia, to develop Xanamem as a promising new treatment for Alzheimer's disease.

This progress continued in June, with the Company successfully enrolling the first two US patients into the trial – highlighting the global reach of XanADu and the success in taking Australian biotech research capability to the US market.

XanADu represents a landmark in the global search for an effective treatment for Alzheimer's disease and reinforces Australia's role at the forefront of Alzheimer's research. Xanamem is a promising new approach to treating this devastating disease at a time when several high-profile drug trials based on more traditional approaches have failed.

Additional trial sites in Australia, the US and the UK are expected to soon start recruiting patients, with the final patient planned to be enrolled in Q4 2018, and top-line results for the trial in Q1 2019.

XanADu is a 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.

It is planned to enrol 174 patients at 20 research sites across the US, UK and Australia. 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 location of study sites open for patient recruitment.

### *Xanamem Phase II trial in Diabetes Cognitive Impairment*

Over the next few months Actinogen Medical will provide updates on an anticipated second Phase II trial of Xanamem, in the treatment of Diabetes Cognitive Impairment. This trial has been proposed, and would be conducted, by the University of Edinburgh, Actinogen Medical's in-licensing partner and largest shareholder.

Success with this Phase II Diabetes Cognitive Impairment trial would reinforce the potential of Xanamem to treat multiple conditions, due to its novel mechanism of action of inhibiting the excess production of the stress hormone cortisol.

As well as Alzheimer's and Diabetes Cognitive Impairment, there is promise for the drug in the management of a number of other conditions including post-traumatic stress disorder and post-myocardial infarction.

### **Financial and Corporate Update**

#### *Presentation at BIO 2017*

At the end of June, Actinogen Medical's CEO Dr Bill Ketelbey presented at the BIO International Convention in San Diego. This annual convention is hosted by the Biotechnology Innovation Organisation and is the largest global meeting for the biotechnology industry. It attracts the biggest names in biotechnology to network on new opportunities and potential partnerships, and offered Actinogen Medical unparalleled networking opportunities to showcase Xanamem and the quality research that supports its development.

#### *Solid cash position*

Actinogen Medical ended the quarter with \$3.989 million cash in the bank

### **Outlook**

The recruitment of the first patients in Australia and the US into XanADU during the quarter represents a significant milestone in terms of the progress and momentum with Actinogen's landmark Phase II clinical trial. Actinogen now expects to recruit the first UK patient within weeks and to recruit more patients across trial sites in the three countries during the September quarter.

The Company remains focused on ensuring the trial progresses as planned and looks forward to updating the market on its progress over the near to medium term. Topline trial results are expected in early 2019.

"We are delighted to have had such strong momentum behind XanADu, a ground-breaking trial that shows Australia is leading the way in developing this promising new treatment for Alzheimer's disease," said Dr Bill Ketelbey, CEO of Actinogen Medical.

"Xanamem could potentially provide one of the more significant contributions to alleviating the burden of Alzheimer's disease – a disease for which new treatments are desperately needed. We look forward to continuing our recruitment for this trial over the coming quarter and to updating our progress on the planned Diabetes Cognitive Impairment trial, an important step in reinforcing Xanamem's potential to treat multiple diseases."

### **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 Xanamem™ 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\$2 trillion 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, will enrol 174 patients at 20 research sites across Australia, the UK and the USA. Patient recruitment into XanADu will begin in Q2 2017 – topline results are expected in Q1 2019. The trial is registered on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) with the identifier: NCT02727699.

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 June 2017

<b>Consolidated statement of cash flows</b>	<b>Current quarter</b>	<b>Year to date</b>
	<b>\$A'000</b>	<b>(12 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	(1,331)	(3,223)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(62)	(172)
(d) leased assets	-	-
(e) staff costs	(53)	(281)
(f) administration and corporate costs	(102)	(409)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	17	37
1.5 Interest and other costs of finance paid	(3)	(8)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	5	2,829
1.8 Other (provide details if material)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(1,529)</b>	<b>(1,227)</b>

<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire:		
(a) property, plant and equipment	-	(1)
(b) businesses (see item 10)	-	-
(c) investments	-	-

<b>Consolidated statement of cash flows</b>	<b>Current quarter</b>	<b>Year to date (12 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	19	51
(d) intellectual property	-	-
(e) other non-current assets	-	-
<b>2.3 Cash flows from loans to other entities</b>	-	-
<b>2.4 Dividends received (see note 3)</b>	12	118
<b>2.5 Other (provide details if material)</b>	-	-
<b>2.6 Net cash from / (used in) investing activities</b>	<b>31</b>	<b>168</b>
<b>3. Cash flows from financing activities</b>		
3.1 Proceeds from issues of shares	-	-
3.2 Proceeds from issue of convertible notes	-	-
3.3 Proceeds from exercise of share options	270	270
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 (provide details if material)	-	-
<b>3.10 Net cash from / (used in) financing activities</b>	<b>270</b>	<b>270</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	5,217	4,778
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(1,529)	(1,227)
4.3 Net cash from / (used in) investing activities (item 2.6 above)	31	168
4.4 Net cash from / (used in) financing activities (item 3.10 above)	270	270

<b>Consolidated statement of cash flows</b>		<b>Current quarter</b>	<b>Year to date (12 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>3,989</b>	<b>3,989</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	1,758	2,023
5.2	Call deposits	2,232	3,194
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>3,989</b>	<b>5,217</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	139
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.		

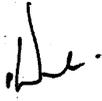
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9. <b>Estimated cash outflows for next quarter</b>	\$A'000
9.1 Research and development	1,825
9.2 Product manufacturing and operating costs	-
9.3 Advertising and marketing	60
9.4 Leased assets	-
9.5 Staff costs	27
9.6 Administration and corporate costs	129
9.7 Other (provide details if material)	-
<b>9.8 Total estimated cash outflows</b>	<b>2,041</b>

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: .....  
**Company Secretary**

Date: 26 July 2017

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.