

# **September Quarterly Update**

- Strong operational progress achieved during the September quarter, with patient recruitment building steadily for XanADu, Actinogen's phase II trial in Alzheimer's disease
- All 20 trial sites across Australia, the UK and the US are now active
- XanADu trial had enrolled 33 patients by the end of the quarter, with some patients already completing the trial
- \$2.4 million cash in the bank as at 30 September 2017, plus an estimated \$1.2 million R&D Tax rebate expected in coming weeks

**Sydney, 30 October 2017: Actinogen Medical (ASX: ACW)** has today submitted its Appendix 4C for the three-month period ended 30 September 2017 and is pleased to release its Quarterly Activities Report.

### **Clinical development progress**

XanADu trial reports steady progress

XanADu is Actinogen's proof-of-concept clinical trial evaluating the safety, tolerability and efficacy of the Company's drug Xanamem<sup>™</sup> in patients with mild Alzheimer's disease. The first patient was treated at the study's Central Coast Neurosciences Research site in New South Wales, Australia in May 2017. This very significant milestone was rapidly followed by treatment of the first US patient in June 2017.

Building on these significant milestones, the Company continued to make steady progress with the trial throughout the quarter. It successfully recruited its first UK patient in mid-August, signalling enrolment momentum for the trial across all three of its geographic territories. All 20 study sites in the US, the UK and Australia are now active.

Recruitment into the XanADu study has progressed steadily over the period, with 33 trial patients enrolled by the end of the quarter. This represents nearly 20% of the total number of patients required for the study (174 patients) and marks solid progress from the trial sites and clinical investigators.

Significantly, the first patient to complete the full 12-week treatment period and the 4-week follow up phase was announced in early September, signalling another important milestone for the Company. Additional patients have since completed the trial.

#### Other medical indications for Xanamem

In addition to Alzheimer's disease, Xanamem has the potential to be used in the management of a number of other conditions, including Diabetes Cognitive Impairment, post-traumatic stress disorder, post-myocardial infarction, Parkinson's disease, epilepsy and schizophrenia. The common feature of all these conditions is raised cortisol – the naturally occurring "stress hormone". Xanamem presents an effective way to decrease cortisol levels and possibly manage these conditions. The Company continues to investigate the potential for the drug in these indications and is working closely with its clinical development partner, the University of Edinburgh in the UK, to design the optimal development pathway for the drug in Diabetes Cognitive Impairment.

#### Intellectual Property Strengthened

During the quarter, the Company's patent portfolio was strengthened when the Canadian Intellectual Property Office granted a further key patent for Xanamem. This Canadian patent represents the final major market patent to be granted for Xanamem.

The Company now holds key patents for Xanamem in all major geographic markets, including the USA, UK, EU, Japan, China, Canada and Australia. These patents extend out to at least 2031, offering the Company strong intellectual property protection.

#### **Corporate and Financial Update**

#### Corporate

During the quarter, Dr Anton Uvarov stepped down from his role as non-executive director of the Company. Dr Uvarov was heavily involved in shaping the development pathway for Xanamem. The Company thanked him for his invaluable contribution to the Company during his tenure on the Board and wished him well for his future endeavours.

Actinogen CEO, Dr Bill Ketelbey presented at Bioshares Biotech 2017 Summit in Queenstown, New Zealand in July 2017. The Bioshares Biotech Summit is an annual industry event sponsored by Bioshares, Australia's leading biotech investment report. Dr Ketelbey's presentation, entitled "Xanamem for Alzheimer's disease" was well received at the Summit.

The Bioshares summit follows an equally successful participation by Actinogen Medical's CEO, Dr Bill Ketelbey at the BIO International Convention in San Diego in late June. This annual convention is the largest global convention for the biotechnology industry and attracts the biggest companies in the biotechnology sector to discuss new opportunities and potential partnerships. It offered Actinogen Medical unparalleled networking opportunities to showcase Xanamem and the quality research that supports its development. Actinogen Medical formally met with 28 pharmaceutical and biotechnology companies at the Convention.

#### **Financials**

With Actinogen's XanADu trial building towards full patient recruitment capacity during the quarter, the Company reports that research and development costs were \$1.4 million, broadly in line with the previous quarter. Other costs remained stable, with total costs reaching \$1.6 million for the quarter.

Actinogen Medical ended the quarter with \$2.4 million cash in the bank, and pending a final review and approval by the ATO the Company expects to receive an estimated \$1.2 million R&D rebate in the near term.

#### **Outlook**

During the quarter, it was reported that dementia, including Alzheimer's disease, has now risen to become the leading cause of death in Australian women, and is the second leading cause of death in Australians overall. These sobering statistics were released by the Australian Bureau of Statistics at the end of September 2017 and highlight the concerning public health crisis that Alzheimer's disease poses to Australians, and indeed more widely across the globe.

Effective new therapies are urgently needed, and Actinogen's Xanamem has a novel way of treating Alzheimer's disease, by lowering cortisol levels in the brain. This distinguishes it from other potential treatments in development or on the market. With the XanADu trial now 20% recruited, the development of Xanamem is gaining momentum and the Company is confident that the trial and Xanamem have the potential to make a significant contribution to managing the substantial health global problem that Alzheimer's disease presents.

"Dementia, including Alzheimer's disease, has become the biggest public health issue of our time. Never has it been more crucial for the medical world to focus on finding new effective treatments for this disease. With Xanamem's novel mechanism of action and our Phase II trial in Alzheimer's disease, XanADu, steadily recruiting patients, we believe that Actinogen's drug has enormous potential to provide an effective treatment for Alzheimer's disease and help manage this growing health crisis," said Dr Bill Ketelbey, CEO of Actinogen Medical.

#### **ENDS**

#### **Actinogen Medical**

Dr. Bill Ketelbey CEO & Managing Director P: +61 2 8964 7401

E: bill.ketelbey@actinogen.com.au



#### **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\$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  $11\beta$ -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. 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.

+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 2017	

Con	solidated 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	(1,358)	(1,358)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(43)	(43)
	(d) leased assets	-	-
	(e) staff costs	(29)	(29)
	(f) administration and corporate costs	(162)	(162)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	3	3
1.5	Interest and other costs of finance paid	(1)	(1)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other (provide details if material)	-	-
1.9	Net cash from / (used in) operating activities	(1,590)	(1,590)

2.	Cash flows from investing activities		
2.1	Payments to acquire:		
	(a) property, plant and equipment	-	-
	(b) businesses (see item 10)	-	-
	(c) investments	(13)	(13)

<sup>+</sup> See chapter 19 for defined terms

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Cons	solidated 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 (see note 3)	18	18
2.5	Other (provide details if material)	-	-
2.6	Net cash from / (used in) investing activities	5	5
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 (provide details if material)	-	-
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	3,989	3,989
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,590)	(1,590)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	5	5
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	-

<sup>+</sup> See chapter 19 for defined terms 1 September 2016

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Con	solidated 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	-	-
4.6	Cash and cash equivalents at end of quarter	2,404	2,404

Note: The Company expects to receive an estimated \$1.2 million R&D Rebate in the near term, pending final review and approval by the ATO.

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	1,187	1,758
5.2	Call deposits	1,217	2,231
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)	2,404	3,989

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	122
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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<sup>+</sup> See chapter 19 for defined terms

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.

9.	Estimated cash outflows for next quarter	\$A'000
9.1	Research and development	1,575
9.2	Product manufacturing and operating costs	-
9.3	Advertising and marketing	52
9.4	Leased assets	-
9.5	Staff costs	27
9.6	Administration and corporate costs	85
9.7	Other (provide details if material)	-
9.8	Total estimated cash outflows	1,739

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	-	-
	Total net assets	-	-
10.5	Nature of business	-	-

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<sup>+</sup> See chapter 19 for defined terms

### **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.

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Sign here: Date: 30 October 2017

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.
- 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.

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<sup>+</sup> See chapter 19 for defined terms