

March quarterly update

- Significant progress achieved with XanADu, Actinogen Medical's Phase II clinical trial of Xanamem™ in Alzheimer's disease
- 17 of a total planned 20 trial sites globally have been selected, with four of these actively recruiting patients.
- Treatment of first patient expected to start within weeks.
- 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 disease research
- Recruitment follows regulatory approval received for XanADu in the US, the UK and Australia during the quarter
- Healthcare industry and venture capital veteran, Dr Geoff Brooke, appointed as Chairman
- Cash at 31st March 2017 of \$5.2 million

Sydney, 26 April 2017: Actinogen Medical (ASX: ACW) is pleased to provide a summary of its progress over the quarter ended 31 March 2017.

Clinical Development Progress

Significant progress achieved with XanADu trial

During the quarter, Actinogen Medical achieved substantial progress with XanADu, its ground-breaking Phase II clinical trial of Xanamem™ in Alzheimer's disease.

Out of the total planned 20 trial sites for XanADu globally, 17 have been selected and four of these sites are actively recruiting patients.

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 disease research. Xanamem represents a new approach to treating the disease at a time when several high-profile drug trials based on more traditional approaches have failed.

The drug's novel mechanism of action differentiates it from other Alzheimer's drugs under development. It has been specifically designed to block excess production of cortisol, the stress hormone, in the areas of the brain most affected by Alzheimer's disease. Chronically raised cortisol levels have been strongly associated with Alzheimer's disease and lowering cortisol in the brain is an important new target for treating the disease.

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 will enrol 174 patients at 20 research sites across the US, UK and Australia. The trial is registered on 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.

Regulatory approval for XanADu

During the quarter, Actinogen Medical received approval to conduct XanADu from the regulatory authorities in the US, the UK and Australia.

These regulatory approvals provide approval to progress the development of Xanamem in the treatment of Alzheimer's disease and underscore the depth and quality of Actinogen's existing research data on Xanamem.

Actinogen received approval from the US Food and Drug Administration in January and the UK Medicines and Healthcare products Regulatory Agency (MHRA) in February. In March, the Company received approval from the Australian Therapeutic Goods Administration (TGA) – the final regulatory approval required for the Company to begin actively recruiting patients in the three countries where the study will be conducted: the US, the UK and Australia.

AIBL study provides promising evidence for the potential of cortisol inhibition in Alzheimer's disease

In January, the Australian Imaging, Biomarker & Lifestyle Flagship Study of Ageing (AIBL) study was published, adding to the growing number of independent studies supporting the strong association between cortisol and the development and progression of Alzheimer's disease.

The AIBL study provided very promising evidence for the potential of cortisol inhibition to prevent the cognitive decline of Alzheimer's disease and provides further strong validation for the ongoing development of Xanamem in the treatment of Alzheimer's disease. It concluded that those subjects with a higher blood cortisol had a much greater chance of developing Alzheimer's disease.

The AIBL study, which is part-funded by the CSIRO and a number of universities, reported on 416 healthy elderly Australians followed over 6 years.

Xanamem Phase I human trial results published in prestigious medical journal

In February, results of the Phase I human trials of Xanamem were published in the British Journal of Pharmacology. These were the first results published of Xanamem research from human trials. The data demonstrated that the orally administered drug inhibits the production of cortisol in healthy volunteers and that it reaches the brain at concentrations predicted to inhibit excess cortisol production in the brain.

Xanamem Phase II trial in Diabetes Cognitive Impairment

Over the next few months Actinogen Medical will provide updates on a proposed second Phase II trial of Xanamem, in the treatment of Diabetes Cognitive Impairment. This trial has been proposed by the University of Edinburgh, Actinogen Medical's in-licensing partner and largest shareholder, and planning is well underway to start the trial in 2017.

Financial and Corporate Update

Appointment of new Chairman

During the quarter, Actinogen Medical was delighted to appoint healthcare industry and venture capital veteran, Dr Geoff Brooke, as its new Chairman.

His appointment adds significant life science and financial expertise to the Actinogen Board, with Dr Brooke having 30 years' international experience as the founder, lead investor and/or Chairman/Director of numerous healthcare companies with a realised value of more than \$1.5 billion.

Most notably, he was the Managing Director and Founder of leading life sciences venture capital firm, GBS Ventures - one of Asia Pacific's premier investors in the healthcare space. There, Dr Brooke was responsible for GBS's healthcare venture activity in the region and raised \$450 million in venture and private equity funds, focused on biopharmaceuticals, medical devices and services.

Dr Brooke now acts a private investor in, and independent director for, a number of small to medium-sized Australian and US private and public companies, including Non-Executive Director for ASX-listed company, Acrux Limited (ASX:ACR).

Solid cash position

Actinogen Medical ended the quarter with \$ 5.2 million cash in the bank.

Outlook

Actinogen Medical has made significant progress during the quarter with XanADu and expects to recruit the first patient for this landmark trial within weeks.

The Company remains focused on ensuring the trial progresses as expected 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 have made excellent progress over the past few months with XanADu and expect to announce the successful recruitment of the first patient imminently. This groundbreaking trial shows that Australia is leading the way in developing this promising new treatment for Alzheimer's disease," said Dr Bill Ketelbey, CEO of Actinogen Medical.

"The development of Xanamem could potentially be one of the most significant contributions Australian clinical development will make to the management of Alzheimer's disease – a disease presenting as the next major global health challenge for which new treatments are desperately needed."

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 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 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")

31 March 2017

Consolidated statement of cash flows	Current quarter	Year to date
	\$A'000	(9 months)
		\$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers		
1.2 Payments for		
(a) research and development	(519)	(1,892)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(5)	(110)
(d) leased assets	-	-
(e) staff costs	(43)	(228)
(f) administration and corporate costs	(94)	(307)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	6	20
1.5 Interest and other costs of finance paid	(1)	(5)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	40	2,824
1.8 Other (provide details if material)	-	-
1.9 Net cash from / (used in) operating activities	(616)	302
2. Cash flows from investing activities		
2.1 Payments to acquire:		
(a) property, plant and equipment	-	(1)
(b) businesses (see item 10)	-	-
(c) investments	-	-

Consolidated statement of cash flows	Current quarter	Year to date (9 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	(19)	32
(d) intellectual property	-	-
(e) other non-current assets	-	-
2.3 Cash flows from loans to other entities	-	-
2.4 Dividends received (see note 3)	40	106
2.5 Other (provide details if material)	-	-
2.6 Net cash from / (used in) investing activities	21	137
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	5,812	4,778
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(616)	302
4.3 Net cash from / (used in) investing activities (item 2.6 above)	21	137
4.4 Net cash from / (used in) financing activities (item 3.10 above)	-	-

Consolidated statement of cash flows		Current quarter	Year to date (9 months)
		\$A'000	\$A'000
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of quarter	5,217	5,217

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	2,023	2,598
5.2	Call deposits	3,194	3,214
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)	5,217	5,812

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	127
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 <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.		

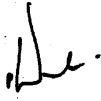
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9. Estimated cash outflows for next quarter	\$A'000
9.1 Research and development	960
9.2 Product manufacturing and operating costs	-
9.3 Advertising and marketing	8
9.4 Leased assets	-
9.5 Staff costs	57
9.6 Administration and corporate costs	110
9.7 Other (provide details if material)	-
9.8 Total estimated cash outflows	1,135

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:
Company Secretary

Date: 26 April 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.