

ASX ANNOUNCEMENT**March 2019 Quarterly Update**

- **First participant dosed in new Xanamem study: XanaHES**
- **DSMB reaffirms XanADu trial for third and final time**
- **Company reaffirms it remains on track to report XanADu results in less than two months**
- **Corporate update: New Non-Executive Director appointed**
- **Future outlook and new clinical development opportunities for Xanamem**

Sydney 24 April 2019: Actinogen Medical ASX: ACW ('ACW' or 'the Company') today submitted its Appendix 4C and quarterly update report for the three-month period ended 31 March 2019.

Operational Update**First participant dosed in new Xanamem study: XanaHES**

In February, Actinogen Medical announced the initial dosing of the first participant in XanaHES, a Phase I dose escalation safety study of Xanamem in healthy elderly volunteers. The study is designed to expand the safety data-set for Xanamem and explores the potential for higher doses of the drug to be used in future trials in Alzheimer's disease and other indications, should they be necessary.

Initial results from the first cohort of the XanaHES study are expected in Q2 2019, around the same time the Phase II XanADu Alzheimer's disease study results read-out.

XanaHES is one of nine additional Xanamem studies initiated over the past few months that have been developed to further expand and enhance the Xanamem data-set.

DSMB reaffirms XanADu trial for third and final time

In March, the XanADu Data Safety Monitoring Board (DSMB) completed its third and final review of XanADu study data, and it reaffirmed its previous recommendations that the trial continue without modification.

For this third meeting, the DSMB reviewed unblinded safety data from 162 patients who had completed the trial. The positive recommendation demonstrates continued validation of the trial and safety of Xanamem, as the DSMB is independent to the Company and is the only body with access to unblinded study data ahead of the read-out.

Actinogen is also pleased to note, and to reaffirm, that the XanADu trial remains on track to report results in Q2 2019.

Corporate Update

Whilst outside the reporting period, in early April Actinogen appointed Malcolm McComas as a Non-Executive Director of the Company. Mr McComas' appointment is highly complementary to the Board's existing mix of expertise and experience and comes at a time as Actinogen enters the next phase of growth, with the XanADu results imminent and the expansion of the Xanamem clinical development plan into new indications, beyond Alzheimer's disease.

Future outlook and new clinical development opportunities for Xanamem

Commenting on the quarterly period, CEO Dr Bill Ketelbey noted: “The March quarter was a particularly productive one where the last patient completed the XanADu study, we re-affirmed the safety of Xanamem in the XanADu trial and we initiated new studies to further enhance the data-set for Xanamem. Currently, we are undergoing the important task of XanADu data entry, checking and quality control prior to the data analysis. Importantly, Actinogen remains on track to announce the results for XanADu in Q2 2019.”

“In early April, we were also pleased to announce an expanded clinical development program for Xanamem, having identified cognitive impairment in mood disorders and schizophrenia as the next indications for development of the drug.”

“Mood disorders – including depression and bipolar disorder – and schizophrenia often present with raised cortisol and are frequently associated with cognitive impairment; they represent a major unmet medical need and important development opportunities for Xanamem, our lead drug candidate,” noted CEO Dr Bill Ketelbey.

ENDS


Actinogen Medical

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About Actinogen Medical

Actinogen Medical (ASX: ACW) is an ASX-listed biotechnology company focused on innovative approaches to treating cognitive decline that occurs in chronic neurological and metabolic diseases. Actinogen Medical is developing its lead compound Xanamem, as a promising new therapy for Alzheimer’s disease, a condition with multibillion-dollar market potential and material human impact. In the US alone, the cost of managing Alzheimer’s disease is estimated to be US\$250bn and is projected 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. In addition, Actinogen is currently planning an expanded clinical development program for Xanamem in cognitive impairment in mood disorders and schizophrenia. In the US alone, the collective economic costs of mood disorders and schizophrenia are estimated to exceed \$550bn, with the burden increasing every year. The cognitive dysfunction associated with these conditions is significantly debilitating for affected patients, with a substantial unmet medical need for novel, improved treatments.

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. There is a strong association between chronic stress and excess cortisol that leads to changes in the brain affecting memory. The 11β-HSD1 enzyme is highly concentrated in the hippocampus and frontal cortex, the areas of the brain associated with cognitive impairment in neurological diseases, including Alzheimer’s disease, mood disorders and schizophrenia.

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.

About XanaHES

XanaHES is a Phase I, randomised, single blinded, central reader blinded, placebo-controlled, dose escalation study to assess the safety and tolerability of Xanamem™ 20mg & 30mg once daily in healthy elderly volunteers. Changes in cognitive performance from baseline to end-of-treatment will be measured as an exploratory efficacy outcome.

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 2019

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	(4,044)	(9,170)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(212)	(536)
(d) leased assets	13	13
(e) staff costs	(35)	(124)
(f) administration and corporate costs	(101)	(356)
1.3 Dividends received	-	-
1.4 Interest received	88	147
1.5 Interest and other costs of finance paid	(2)	(4)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	40	3,218
1.8 Other (provide details if material)	-	-
1.9 Net cash from / (used in) operating activities	(4,253)	(6,812)
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 \$A'000	Year to date (9 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	-	-
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	-	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/Employee)	40	560
3.10 Net cash from / (used in) financing activities	40	8,096
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	15,503	10,004
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(4,253)	(6,812)
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)	40	8,096

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	-	2
4.6	Cash and cash equivalents at end of quarter	11,290	11,290

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	3,190	1,903
5.2	Call deposits	8,100	13,600
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)	11,290	15,503

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 | 200 |
| 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. Includes bonus payment to Managing Director for the achievement of milestones met during calendar 2019.

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	3,228
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	142
9.7 Other	-
9.8 Total estimated cash outflows	3,553


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: 24 April 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.