

ASX ANNOUNCEMENT**June 2019 Quarterly Update**

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- **Development update**
 - **Progress with XanaHES trial – final subject for 20mg cohort enrolled**
 - **Target Occupancy studies: Phase 1 PET study and homogenate binding**
 - **Pre-clinical toxicology studies**
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- **Future Outlook**

Sydney 30 July 2019: Actinogen Medical ASX: ACW ('ACW' or 'the Company') today submitted its Appendix 4C and is pleased to provide this Quarterly Update report for the three-month period ended 30 June 2019.

XanADu Phase II Clinical Trial – further analysis and results update

During the quarter, the Company announced the initial data from XanADu, the Phase II clinical trial of 10 mg daily Xanamem in patients with mild dementia due to Alzheimer's disease.

While the trial did not meet its primary endpoints, Xanamem demonstrated an excellent safety profile and showed a significant pharmacodynamic effect in inhibiting cortisol production.

During the quarter, the Company made good progress on performing deeper analyses of the XanADu data to explore efficacy trends and to identify any specific cognitive domains in which positive trends may be evident. Further analysis will help inform the future development of Xanamem and will be considered alongside other ongoing pre-clinical and clinical studies.

When all study outcomes are known, they will be consolidated and help inform a detailed strategic review of the future development of Xanamem, expected in 3Q CY2019.

Development update

During the quarter, the Company continued to work on enhancing the dataset for Xanamem through the additional ongoing Xanamem studies.

Progress with XanaHES trial – final subject for 20mg cohort enrolled

XanaHES is Actinogen's Phase I safety study of Xanamem in healthy elderly volunteers and is designed to expand the safety dataset at higher doses. The trial will explore the potential use for higher doses of the drug in future trials in Alzheimer's disease and other indications.

As announced on 20th May following a scheduled interim safety review of the XanaHES trial, it was recommended that XanaHES continue, with some protocol enhancements. The Company is pleased to note that the final patient for the 20mg cohort was recently enrolled and that a Dose Escalation Committee will determine if the study should proceed with any further cohorts of patients at higher doses, once all subjects have completed the full 16-week 20mg study.

Actinogen expects to provide full results on the 20mg XanaHES cohort by 4Q CY2019, including the safety profile of 20mg, and the results on the Cogstate cognition test battery.

Target Occupancy studies: Phase 1 PET study and homogenate binding

The Target Occupancy studies are designed to measure the effect of different Xanamem doses on inhibiting the 11 β -HSD1 enzyme in the brain and include a Phase 1 PET scan and homogenate binding studies.

The Target Occupancy Phase I PET study made positive progress over the quarter, with the 10mg and 20mg study cohorts completing the trial. Initial results demonstrate significant inhibition of the 11 β -HSD1 enzyme in the brain and support Xanamem as a potent, orally bioavailable and brain-penetrant 11 β -HSD1 inhibitor.

This study will now proceed with the 5mg and 30mg cohorts to enable a full analysis and understanding of the dose-inhibition response of Xanamem. The study results as a whole will only be discerned once all cohorts have completed the trial, expected in Q3 CY2019.

The homogenate binding studies constitute a suite of in-vitro studies on human brain tissue conducted in the UK and are designed to further confirm and enhance the data and conclusions from the Target Occupancy clinical study, including demonstrating the residual activity of the 11 β -HSD1 enzyme at varying doses of Xanamem.

Pre-clinical toxicology studies

Prior to the commencement of clinical studies with longer-term dosing, regulatory agencies require long-term toxicology studies in two non-primate species. These studies are progressing as planned and will read out over the rest of CY2019 and CY2020. Assuming no toxicology issues arise, it is expected that longer-term clinical trials can commence prior to the completion of these pre-clinical toxicology studies.

Feedback to date has been positive, with no unexpected toxicology or safety concerns associated with long term exposure to Xanamem.

Expansion into new indications

During the quarter, Actinogen announced it would expand the clinical development opportunities for Xanamem and selected cognitive impairment in mood disorders and schizophrenia as the next indications.

A clinical development plan will be drafted for these new indications over the next few months in consultation with an expert Advisory Board, and the Company looks forward to providing an update to the market in due course.

Cognitive impairment in mood disorders and schizophrenia represent a significant unmet medical need and a substantial market opportunity, with limited or no existing therapeutic options available for clinicians and patients.

Manufacturing of Xanamem

The Company recently selected Corden Pharma LLC as its Contract Development and Manufacturing Organisation (CDMO) to optimise the synthesis of Xanamem and scale up the production required for Xanamem's further clinical development.

Financials

The Company reported \$7.672m in cash at the end of the June Quarter which adequately covers the current Xanamem development program and corporate expenses through to the end of 2020. Additionally, the Company expects to receive approximately \$4.6m in FY2019 R&D Tax rebates, in September/October 2019, with a further FY2019 rebate of up to \$0.65m expected thereafter.

Future Outlook


Commenting on the period, CEO Dr Bill Ketelbey noted: "This past quarter was particularly significant for the business, as we announced the XanADu Phase II trial results. The strong pharmacodynamic effects and safety of Xanamem observed, demonstrated the potential for the drug in treating conditions associated with raised cortisol. Given these encouraging results, our focus has been on further analysing this data to better understand Xanamem's optimal clinical opportunity."

"During the quarter, we also progressed various studies which will help inform the future development of Xanamem, especially in relation to dosing and duration of treatment. We are pleased these are on track and that we expect the strategic review for our lead drug candidate to occur in Q3 CY2019."

"The next few months will be important for Actinogen as we expect results for the deeper analysis of the XanADu data as well as updates on XanaHES, Target Occupancy studies and our new indications. I'd like to thank the Actinogen team, investors and all stakeholders for their continued support of the Company as we progress the development of Xanamem and move into the new financial year." said Dr 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. 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")

30 June 2019

Consolidated statement of cash flows	Current quarter	Year to date
	\$A'000	(12 months)
		\$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers		
1.2 Payments for		
(a) research and development	(3,488)	(12,658)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(164)	(700)
(d) leased assets	-	13
(e) staff costs	(34)	(158)
(f) administration and corporate costs	(83)	(439)
1.3 Dividends received	-	-
1.4 Interest received	57	204
1.5 Interest and other costs of finance paid	(3)	(7)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	21	3,239
1.8 Other (provide details if material)	-	-
1.9 Net cash from / (used in) operating activities	(3,694)	(10,506)
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	Year to date (12 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	-	-
(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	77	767
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)	-	560
3.10 Net cash from / (used in) financing activities	77	8,173
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	11,290	10,004
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(3,694)	(10,506)
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)	77	8,173

Consolidated statement of cash flows		Current quarter	Year to date (12 months)
		\$A'000	\$A'000
4.5	Effect of movement in exchange rates on cash held	(1)	1
4.6	Cash and cash equivalents at end of quarter	7,672	7,672

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
5.2	Call deposits	8,100
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

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	136
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	2,736
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	143
9.7 Other	-
9.8 Total estimated cash outflows	3,062

Note: The Company expects to receive approximately \$4.6m in FY2019 R&D Tax rebates in September/October 2019, with a further FY2019 rebate of up to \$0.65m expected thereafter.

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: 30 July 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.