



ASX ANNOUNCEMENT

Actinogen March 2023 Quarterly Activity Report and Appendix 4C

Sydney, 24 April 2023. Actinogen Medical ASX: ACW (“ACW” or “the Company”) is pleased to announce the release of its quarterly activity report and Appendix 4C for the three-month period ended 31 March 2023.

Key Highlights

- **Advancing Phase 2 clinical trial programs:**
 - Ongoing enrolment in the XanaCIDD Phase 2a trial in patients with persistent major depressive disorder (MDD) and cognitive impairment despite a standard course of anti-depressant therapy.
The XanaCIDD trial is a six-week proof-of-concept, placebo-controlled, parallel group design trial in 160 patients. Xanamem® 10 mg once daily or placebo is added to the existing anti-depressant therapy and effects on cognition and depression are assessed.
 - Continued preparations for the commencement of the XanaMIA Phase 2b clinical trial of Xanamem in patients with early Alzheimer’s disease (AD).
The XanaMIA trial will enrol 330 patients with mild AD and progressive disease, determined by clinical criteria and confirmed by an elevated level of pTau181 protein in the blood. Patients will be randomized to one of three parallel groups (5 mg or 10 mg Xanamem, or placebo, once daily).
- **Appointed eminent US-based neurologist and clinical trials specialist Dr Dana Hilt MD as Chief Medical Officer (CMO) effective 1 February**
- **Appointed highly credentialled immunologist and experienced US-based biopharma executive Dr Nicki Vasquez to the board as an independent Non-Executive Director effective 1 March**
- **CEO presented at key conferences and stakeholder meetings including:**
 - The Sachs Associates Annual Neuroscience Innovation Forum in San Francisco on 8 January where Dr Gourlay presented the company’s latest clinical data. He also conducted meetings at BIO Partnering @ JPM associated with the J P Morgan Annual Healthcare Conference from 9 to 12 January as well as the concurrent H C Wainwright Bioconnect Conference
 - The Spark Plus Biotech Conference in Singapore on 24 March where Dr Gourlay’s presentation focused on four main topics including data showing Xanamem activity in four independent trials, and why anti-amyloid therapies have limited utility and novel therapies are still required for the treatment of AD.
- **Cash balance of \$12.27 million at 31 March 2023.¹**

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¹ Unless stated otherwise, all financial data is in Australian dollars

Dr Steven Gourlay, Actinogen CEO and MD, commented:

“Actinogen was very pleased to make two significant US-based appointments during the March quarter with world-leading neurologist and drug development expert Dr Dana Hilt appointed as CMO and immunologist and experienced biopharma executive Dr Nicki Vasquez appointed as a Non-executive Director.

“The Company continues to enrol and treat patients in its Phase 2a XanaCIDD depression trial which commenced in late December 2022, and to prepare for its upcoming Phase 2b XanaMIA Alzheimer’s disease trial.

“Our small molecule drug Xanamem® has the potential to be an effective low-dose daily oral therapy for the treatment Alzheimer’s disease, depression, and many other neurological conditions where it may be used alone or in combination with other treatments. Xanamem has already been proven to enhance cognition in multiple independent clinical trials with safety demonstrated in more than 300 people treated to date.”

Cash position

Actinogen’s cash balance at 31 March 2023 was \$12.27 million.

Net operating cash outflow for the quarter was \$2.19 million, including R&D spend of \$1.69 million, staff costs of \$0.83 million, administration and corporate costs of \$0.40 million, and the receipt of an additional \$0.48 million R&D tax incentive cash rebate relating to the 2022 financial year.

Consistent with ASX Listing Rule 4.7c.3, item 6 of the attached Appendix 4C of the cashflow report for the quarter included payments to Related Parties of \$0.17 million comprising the salary for the CEO/Managing Director, fees paid to Non-Executive Directors and superannuation.

ENDS

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Announcement authorised by the Board of Directors of Actinogen Medical

About Actinogen Medical

Actinogen Medical (ACW) is an ASX-listed, biotechnology company developing a novel therapy for neurological and neuropsychiatric diseases associated with dysregulated brain cortisol. There is a strong association between cortisol and detrimental changes in the brain, affecting cognitive function, harm to brain cells and long-term cognitive health.

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Cognitive function means how a person understands, remembers and thinks clearly. Cognitive functions include memory, attention, reasoning, awareness and decision-making.

Actinogen is currently developing its lead compound, Xanamem,[®] as a promising new therapy for Alzheimer's Disease and Depression and hopes to study Fragile X Syndrome and other neurological and psychiatric diseases in the future. Reducing cortisol inside brain cells could have a positive impact in these and many other diseases. The cognitive dysfunction, behavioural abnormalities, and neuropsychological burden associated with these conditions is debilitating for patients, and there is a substantial unmet medical need for new and improved treatments.

About Xanamem

Xanamem's novel mechanism of action is to block the production of cortisol inside cells through the inhibition of the 11 β -HSD1 enzyme in the brain. Xanamem is designed to get into the brain after it is absorbed in the intestines upon swallowing its capsule.

Chronically elevated cortisol is associated with cognitive decline in Alzheimer's Disease and excess cortisol is known to be toxic to brain cells. Cognitive impairment is also a feature in Depression and many other diseases. Cortisol itself is also associated with depressive symptoms and when targeted via other mechanisms has shown some promise in prior clinical trials.

The Company has studied 11 β -HSD1 inhibition by Xanamem in more than 300 volunteers and patients, so far finding a statistically significant improvement in working memory and attention, compared with placebo, in healthy, older volunteers in two consecutive trials and clinically significant improvements in functional and cognitive ability in patients with biomarker-positive mild AD. Previously, high levels of target engagement in the brain with doses as low as 5 mg daily have been demonstrated in a human PET imaging study. A series of Phase 2 studies in multiple diseases is being conducted to further confirm and characterize Xanamem's therapeutic potential.

Xanamem is an investigational product and is not approved for use outside of a clinical trial by the FDA or by any global regulatory authority. Xanamem[®] is a trademark of Actinogen Medical.

Disclaimer

This announcement and attachments may contain certain "forward-looking statements" that are not historical facts; are based on subjective estimates, assumptions and qualifications; and relate to circumstances and events that have not taken place and may not take place. Such forward looking statements should be considered "at-risk statements" - not to be relied upon as they are subject to known and unknown risks, uncertainties and other factors (such as significant business, economic and competitive uncertainties / contingencies and regulatory and clinical development risks, future outcomes and uncertainties) that may lead to actual results being materially different from any forward looking statement or the performance expressed or implied by such forward looking statements. You are cautioned not to place undue reliance on these forward-looking statements that speak only as of the date hereof. Actinogen Medical does not undertake any obligation to revise such statements to reflect events or any change in circumstances arising after the date hereof, or to reflect the occurrence of or non-occurrence of any future events. Past performance is not a reliable indicator of future performance. Actinogen Medical does not make any guarantee, representation or warranty as to the likelihood of achievement or reasonableness of any forward-looking statements and there can be no assurance or guarantee that any forward-looking statements will be realised.

ACTINOGEN MEDICAL ENCOURAGES ALL CURRENT INVESTORS TO GO PAPERLESS BY REGISTERING THEIR DETAILS WITH THE DESIGNATED REGISTRY SERVICE PROVIDER, AUTOMIC GROUP.

[®] Xanamem is a registered trademark of Actinogen Medical Limited

Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity

ACTINOGEN MEDICAL LIMITED

ABN

14 086 778 476

Quarter ended ("current quarter")

31 March 2023

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (9 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers		
1.2 Payments for		
(a) research and development	(1,690)	(6,558)
(b) product manufacturing and operating costs		
(c) advertising and marketing		
(d) leased assets		
(e) staff costs	(832)	(2,354)
(f) administration and corporate costs	(402)	(1,097)
1.3 Dividends received (see note 3)		
1.4 Interest received	138	279
1.5 Interest and other costs of finance paid	(4)	(14)
Income taxes paid		
1.7 Government grants and tax incentives	479	4,644
1.8 Other (working capital movements)	116	88
1.9 Net cash from / (used in) operating activities	(2,195)	(5,012)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities		
(b) businesses		
(c) property, plant and equipment	(18)	(31)
(d) investments		
(e) intellectual property		
(f) other non-current assets		
2.2 Proceeds from disposal of:		
(a) entities		
(b) businesses		

Appendix 4C
Quarterly cash flow report for entities subject to Listing Rule 4.7B

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (9 months) \$A'000
(c) property, plant and equipment		
(d) investments		
(e) intellectual property		
(f) other non-current assets		
2.3 Cash flows from loans to other entities		
2.4 Dividends received (see note 3)		
2.5 Other (provide details if material)		
2.6 Net cash from / (used in) investing activities	(18)	(31)
3. Cash flows from financing activities		
3.1 Proceeds from issues of equity securities (excluding convertible debt securities)		
3.2 Proceeds from issue of convertible debt securities		
3.3 Proceeds from exercise of options	-	903
3.4 Transaction costs related to issues of equity securities or convertible debt securities		
3.5 Proceeds from borrowings		
3.6 Repayment of loan shares by Managing Director		
3.7 Transaction costs related to loans and borrowings		
3.8 Dividends paid		
3.9 Other		
3.10 Net cash from / (used in) financing activities	-	903
4. Net increase / (decrease) in cash and cash equivalents for the period		
4.1 Cash and cash equivalents at beginning of period	14,483	16,370
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(2,195)	(5,012)
4.3 Net cash from / (used in) investing activities (item 2.6 above)	(18)	(31)
4.4 Net cash from / (used in) financing activities (item 3.10 above)	-	903
4.5 Effect of movement in exchange rates on cash held	1	41
4.6 Cash and cash equivalents at end of period	12,271	12,271

Quarterly cash flow report for entities subject to Listing Rule 4.7B

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	2,271	2,483
5.2	Call deposits	10,000	12,000
5.3	Bank overdrafts		
5.4	Other – restricted cash re office lease		
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	12,271	14,483

6.	Payments to related parties of the entity and their associates	Current quarter \$A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	172
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.

Payments relate to salaries & fees paid to Directors of the Company during the quarter.

7.	Financing facilities <i>Note: the term "facility" includes all forms of financing arrangements available to the entity. Add notes as necessary for an understanding of the sources of finance available to the entity.</i>	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
7.1	Loan facilities		
7.2	Credit standby arrangements		
7.3	Other (please specify)		
7.4	Total financing facilities		
7.5	Unused financing facilities available at quarter end		
7.6	Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.		

Appendix 4C
Quarterly cash flow report for entities subject to Listing Rule 4.7B

8. Estimated cash available for future operating activities	\$A'000
8.1 Net cash from / (used in) operating activities (item 1.9)	(2,195)
8.2 Cash and cash equivalents at quarter end (item 4.6)	12,271
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	12,271
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	5.59
<i>Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.</i>	
8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:	
8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?	
Answer: N/A	
8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?	
Answer: N/A	
8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?	
Answer: N/A	
<i>Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.</i>	

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.

Date: 24 APRIL 2023

Authorised by: By the Board
(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
2. If this quarterly cash flow 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 cash flow 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.
4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee – eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.