ASX ANNOUNCEMENT

Actinogen June 2023 Quarterly Activity Report and Appendix 4C

Sydney, 31 July 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 30 June 2023.

- **Capital raising trading halt on 31 July**
    - A two-day capital raising trading halt was announced today. More information will follow at the conclusion of the trading halt.
- **XanaCIDD Phase 2a clinical trial progress:**
    - After the start-up phase, enrolment is now progressing well in the XanaCIDD Phase 2a trial in 160 patients with cognitive impairment associated with persistent major depressive disorder (MDD). All Australian sites are now open for recruitment and actively screening, enrolling, and treating patients, with enrolment approaching 25%.
    - So that timelines are maintained, new sites are being opened in the USA to compensate for industry-wide regulatory delays in the UK.[1] Results are still anticipated in H1CY2024.
- **XanaMIA Phase 2b clinical trial progress:**
    - Commencement activities for the XanaMIA Phase 2b clinical trial of Xanamem® in patients with mild to moderate Alzheimer's disease (AD) continue. Numerous enthusiastic global trial centers have been identified and are undergoing qualification and start-up processes. Countries selected for participation to date are Australia, Canada, the USA, Singapore, and South Korea. The trial is expected to commence in the current half year. Results are still anticipated in H2CY2025
    - On 5 June, the Company submitted updated regulatory documentation to the FDA including the updated clinical protocol and quality documentation for the new tablet formulation of Xanamem. On 4 July, the 30-day waiting period for FDA feedback passed, allowing the Company to proceed with the trial.
- **Manufacturing:**
    - Successfully completed development and manufacturing of the new and to-be-marketed tablet formulation for use in the XanaMIA Phase 2b clinical trial. This is a notable milestone that enables the Company's planned expansion of its trial program upon a positive result from its phase 2 depression trial next year.

[1] Industry-wide delays in The Medicines and Healthcare products Regulatory Agency (MHRA) approval processes has prevented XanaCIDD trial center activation so far in the UK

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- **Expanding the team:**
    - Continued to fill vital operational roles to ensure the success of the clinical development program, including the appointment of a Global AD Program Lead based in the USA, along with several clinical operations team members in Australia. The Actinogen "hands on" operational model aims to increase trial quality and decrease cost by using Actinogen staff to closely supervise the performance of trial centers and other partner organizations.
- **CEO and CMO presented at key international conferences and industry meetings including:**
    - The BIO International Convention in Boston, USA on 5 June where Dr Gourlay and Dr Hilt met with international investors and prospective biopharma partners
    - The National Dementia Conference in Melbourne on 21 June. Dr Gourlay provided a keynote presentation on the small number of oral therapies in development for AD with credible cognitive data competing with the Xanamem program
    - The Alzheimer's Association International Conference (AAIC) in Amsterdam, The Netherlands on 17-20 July. Dr Hilt presented an academic poster which summarized data from three earlier Phase 1 and 2a Xanamem trials and concluded that Xanamem displays activity in multiple domains of cognition, and that treatment with Xanamem results in clinically meaningful slowing of disease
    - The 2023 Bioshares Biotech Summit in Hobart on 25 July, which brings together biotech companies and investors for company presentations, industry engagement and investor meetings. Dr Gourlay's presentation summarized the Xanamem story and near-term Phase 2 clinical and regulatory milestones.
- **Cash balance of $8.46 million at 30 June 2023.**[2]

Dr Steven Gourlay, Actinogen's CEO and MD, said:

"Actinogen is particularly pleased to see increasing enrolment of Australian participants in our XanaCIDD Phase 2a trial in patients with cognitive impairment associated with persistent MDD. With the added contribution of US and UK trial centers, we are on track for results by the middle of 2024, which is now less than a year away."

'The completed production of a to-be-marketed tablet formulation is a major milestone for our manufacturing team. Ready access to these tablets sets the Company up for strategic collaborations and the planned expansion of the clinical trial program upon positive Phase 2 XanaCIDD results next year."

Cash position

Actinogen's cash balance at 30 June 2023 was $8.46 million.

Net operating cash outflow for the quarter was $3.77 million, including R&D spend of $2.59 million and staff costs of $0.70 million. Administration and corporate costs of $0.54 million were higher than the prior quarter primarily due to the payment of annual insurance renewals and increased investor relations activity.

[2] Unless stated otherwise, all financial data is in Australian dollars

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 $0.18 million comprising the salary for the CEO/Managing Director, fees paid to Non-Executive Directors and superannuation.

ENDS

Investors

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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.

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.

Current and Upcoming Clinical Trials

The **XanaCIDD Phase 2a depression trial** is a double-blind, six-week proof-of-concept, placebo-controlled, parallel group design trial in 160 patients. Patients are evenly randomized to receive Xanamem 10 mg once daily or placebo, in some cases in addition to their existing antidepressant therapy, and effects on cognition and depression are assessed.

The **XanaMIA Phase 2b Alzheimer's disease trial** is a double-blind, 36-week treatment, placebo-controlled, parallel group design trial in 330 patients with mild to moderate AD and progressive disease, determined by clinical criteria and confirmed by an elevated level of pTau181 protein in blood. Patients receive Xanamem 5 mg or 10 mg, or placebo, once daily, and effects on cognition, function and progression of Alzheimer's disease are assessed. Thus, Xanamem is being assessed in this trial for its potential effects as a both a cognitive enhancer and a disease course modifier.

About Xanamem

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

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

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associated with depressive symptoms and when targeted via other mechanisms has shown some promise in prior clinical trials.

The Company has studied 11β-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.

Appendix 4C

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

Name of entity

ACTINOGEN MEDICAL LIMITED

ABN	**Quarter ended ("current quarter")**
14 086 778 476	30 June 2023

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (12 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers		
1.2	Payments for		
	(a) research and development	(2,590)	(9,148)
	(b) product manufacturing and operating costs		
	(c) advertising and marketing		
	(d) leased assets		
	(e) staff costs	(697)	(3,051)
	(f) administration and corporate costs	(535)	(1,632)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	87	366
1.5	Interest and other costs of finance paid	(4)	(18)
	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	4,644
1.8	Other (working capital movements)	(26)	62
1.9	**Net cash from / (used in) operating activities**	**(3,765)**	**(8,777)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities		
	(b) businesses		
	(c) property, plant and equipment	(6)	(37)
	(d) investments		
	(e) intellectual property		
	(f) other non-current assets		
2.2	Proceeds from disposal of:		
	(a) entities		
	(b) businesses		

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 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**	**(6)**	**(37)**

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	12,271	16,370
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,765)	(8,777)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(6)	(37)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	903
4.5	Effect of movement/adjustment in exchange rates on cash held	(40)	1
4.6	**Cash and cash equivalents at end of period**	**8,460**	**8,460**

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	1,460	2,271
5.2	Call deposits	7,000	10,000
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)**	**8,460**	**12,271**

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	183
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 *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.*	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.		

8.	Estimated cash available for future operating activities	$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(3,765)
8.2	Cash and cash equivalents at quarter end (item 4.6)	8,460
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	8,460
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	2.25

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.

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

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.

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: 31 JULY 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.