ASX ANNOUNCEMENT

Actinogen HY2024 financial results – two key phase 2 trials

Sydney, 26 February 2024. Actinogen Medical ASX: ACW ("ACW" or "the Company") is pleased to release its interim financial results for the six months ended 31 December 2023.

Highlights - Continuing to *Follow the Science*:

Received approval of application for a UK Innovation Passport as part of the Innovative Licensing and Access Pathway (ILAP) for Xanamem® in the treatment of Alzheimer's disease

Advancing two major Phase 2 clinical trial programs:

- Enrolment continues to track well in the six-week XanaCIDD Phase 2a Depression clinical trial at Australian and UK sites, which now exceeds 75% of the planned 160 trial participants. Results are expected in Q2 CY2024
- Trial site activation and participant screening has commenced in the XanaMIA Phase 2b Alzheimer's Disease trial. Treatment of the first of 100 participants at Australian sites is expected to begin shortly. Final results are expected in H2CY2025 with an interim analysis due in H1CY2025.

Received a $4.8 million[1] Research & Development (R&D) tax incentive rebate

Completed the development of an improved synthetic process of Xanamem drug substance and manufacture of a 1kg demonstration batch as a prelude to larger scale manufacture

Published Xanamem human brain PET study in peer-reviewed journal, The Journal of Alzheimer's Disease

Initiated strategic changes and additions to the executive and operational teams

Presented at numerous international and Australian AD, investment and partnering meetings

Completed a successful $10 million capital raising in September.

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

"The clear priority for the next 18 months is to deliver high quality results from our two Phase 2 clinical trials. We continue to make excellent progress recruiting participants for our XanaCIDD Phase 2a trial in patients with cognitive impairment associated with persistent major depressive disorder (MDD). Enrolment in that trial now exceeds 75%, and final results are expected to read out in Q2 2024. The first patient in the XanaMIA Phase 2b trial is due to be treated shortly, with initial results in the first half of 2025."

® Xanamem is a registered trademark of Actinogen Medical Limited
[1] All financial data is in Australian dollars unless stated otherwise

Interim Financial Report

Shareholders are encouraged to review the 2024 Interim Financial Report released today in digital format, which provides financial statements and an operating and financial review for the six months ended 31 December 2023, including details supporting the highlights outlined in this announcement.

The Interim Report is available in the Results Centre under the Investor Centre tab of the Company's website https://actinogen.com.au/.

Statutory financial result

The statutory result for the first six months of the 2024 financial year reflects the Company's ongoing investment in developing and advancing its lead molecule Xanamem for the treatment of Alzheimer's disease and depression.

The Net loss after tax for the half year ended 31 December 2023 was $11,556,659 (HY2022: loss of $7,438,708).

The major expenditure item for the half year was Research and Development costs of $8,952,776 (HY2022: $5,384,406), primarily relating to clinical trials.

Financial position

At 31 December 2023, the Company had a Cash and cash equivalents balance of $11,472,389 (31 December 2022: $8,460,074).

Strategy and Outlook

The Company is confident about its prospects in FY2024 and beyond and believes that it has successfully mitigated many drug development risks for the program, including regulatory, manufacturing, non-clinical and clinical risks.

The XanaCIDD Phase 2a depression trial will report results in the second quarter of 2024, using a primary endpoint measuring cognition that was validated by demonstrating Xanamem benefits in two prior volunteer trials. Xanamem effects on depression itself will also be measured.

The second major clinical milestone is the interim analysis of the XanaMIA Phase 2b trial in patients with AD, expected in H1 CY2025. Trial sites have been activated, the first patients have been screened, and the first patient will be treated shortly.

Meanwhile manufacturing, regulatory, clinical pharmacology and nonclinical planning and activities continue in high order to enable rapid expansion on successful Phase 2 results.

We are committed to proactive management of all aspects of our business to ensure the best possible outcomes for shareholders. This includes our current clinical trials program, our forward planning for future trials and eventual drug commercialization and working intensively to mature commercial and development partnership relationships.

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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 220 patients with mild to moderate AD and progressive disease, determined by clinical criteria and confirmed by an elevated level of the pTau181 protein biomarker in blood. Patients receive Xanamem 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 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.