ASX ANNOUNCEMENT

ACW FY2023 results release – following the science

Sydney, 30 August 2023. Actinogen Medical ASX: ACW ("ACW" or "the Company") is pleased to release its results and annual report for the year ended 30 June 2023.

Highlights: 'Following the Science'

Xanamem® program and cortisol target validated by Phase 2a Clinical Biomarker trial results showing large clinical benefit on CDR-SB endpoint in biomarker-positive patients

Advancing two major Phase 2 clinical trial programs:

- Enrolment increasing over the first six months in the XanaCIDD Phase 2a depression clinical trial at Australian sites - UK and US sites opening soon, and results expected in H1CY24
- US Food and Drug Administration (FDA) approval to proceed with XanaMIA Phase 2b Alzheimer's disease trial - startup phase progressing well, and final results expected in H2CY25 with an interim analysis in early CY25
- Completed development and manufacturing of the new and to-be-marketed tablet formulation for use in the XanaMIA Phase 2b clinical trial and all future trials.

Strengthened the team:

- Appointed new independent non-executive director Nicki Vasquez PhD, new CMO Dr Dana Hilt MD, and clinical advisor A/Professor Christopher Chen
- Expanded the operational team by appointing a global project manager in the US and additional clinical trial personnel in Australia.

Completed first and second Clinical Trials Science Forum webinars to inform and educate investors on the science behind Xanamem, anti-amyloid drugs and the Company's clinical trials program

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

Announced a post balance date capital raising on 2 August 2023:

- A non-renounceable pro-rata rights issue offer to existing shareholders to raise a maximum of approximately $10 million (before costs) is currently in progress at the date of this annual report
- The offer to eligible shareholders (holding shares at the Record Date of 14 August 2023) is to:
    - Acquire 1 new share for every 4.54 Shares held at an issue price of 2.5 cents per new share

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- Receive for no additional payment 1 new unlisted option (with an exercise price of 3.75 cents and an expiry date 36 months from the date of issue) for every 2 new shares issued
- Apply for any number of additional shares (and corresponding new options) if shareholders subscribe for their full pro rata entitlement initially (known as a top up offer).

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

"The highlight of the year was the large Xanamem clinical benefit seen in two key endpoints assessing function and cognitive ability in patients with mild Alzheimer's disease who had elevated blood pTau levels (indicating progressive disease). If confirmed in subsequent trials, the clinical benefit for Xanamem would be the largest ever observed for a medication in this disease.

"Actinogen is also 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."

FY2023 Annual Report available today

Shareholders are encouraged to review the 2023 Annual Report released today in digital format, which provides a full account of the Company's activities during the past year including the details supporting the highlights outlined in this announcement.

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

A hard copy version will be distributed in due course to those opting to receive one ahead of the Company's AGM, which will be held in Sydney on 8 November 2023. The AGM will return to an 'in person' format this year. Meeting time and details will be advised with the Notice of Meeting.

Statutory financial result

The statutory result for the 2023 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 after-tax loss for the financial year ended 30 June 2023 was $10,752,270 (FY22: loss of $9,497,370).

The major expenditure item for the year was Research and Development costs of $8,899,947 (FY22: $8,214,847), primarily relating to clinical trials.

Financial position

At 30 June 2023, the Company had a Cash and cash equivalents balance of $8,460,074 (30 June 2022: $16,370,283), and Net Assets of $13,407,215 (30 June 2022: $21,739,877).

The cash balance of $8.5 million at 30 June 2023 will be supplemented by an R&D tax incentive cash refund of approximately $3.8 million expected before the end of calendar 2023. This will be further supplemented by the net proceeds from the $10 million rights issue offer due to close at 7pm, Monday 4 September 2023.

Strategy and Outlook

The Company's strategic priorities focus on three key elements:

- Accelerate clinical development in cognitive impairment
- Forward planning
- Create value from partnerships

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 closely with existing and potential new partners.

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

The Company remains confident about its prospects in FY2024 and beyond. Actinogen is now implementing the XanaCIDD trial that will report results in H1CY 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 early 2025. To have two major clinical readouts in the next 18-month period reflects the successful hard work and dedication of the Actinogen team.

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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.

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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 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.