



ASX ANNOUNCEMENT

ACW FY2022 results release – accelerating the clinical development program

Sydney, 25 August 2022. Actinogen Medical ASX: ACW (“ACW” or “the Company”) is pleased to release its results and annual report for the year ended 30 June 2022.

Key Highlights

Accelerating the Xanamem® clinical development program with a focus on cognition

- Reported strongly positive results for attention and working memory (cognition) in the XanaMIA Part A trial
- Initiated strategic adjustments to prioritize Alzheimer’s Disease (AD) and Cognitive Impairment in Depressive Disorder (CIDD) clinical trial programs where cognition is the primary focus
- Announced high level trial design and commencement of activities for the XanaMIA Part B Phase 2 AD trial and the XanaCIDD Phase 2 Depression trial
- Announced that the Phase 2 biomarker trial data will be available by the end of October and that the final sample size will be approximately 70 participants (post financial year end announcement)
- Finalized a clinical protocol for a strategic collaboration with Oxford University researchers¹
- Established two new Xanamem clinical advisory boards for Depression and FXS programs
- Appointed highly credentialed Chief Medical Officer Professor Paul Rolan and VP Clinical Operations Cheryl Townsend, and continued to expand expertise through appointment of key employees and consultants

Manufacturing

- Continued scale-up manufacturing with Corden Pharma
- Initiated tablet development with Metrics Contract Services

Finances²

- Successfully completed a \$13.3 million capital raising in December 2021 to fund the clinical development pipeline
- Year-end cash balance of \$16.4 million
- Reallocated circa \$12 million of resources from suspended Fragile X Syndrome program to clinical trial programs where cognition is the primary focus

Corporate and Business Development

- Attended and participated in several significant international conferences, events and meetings that facilitated opportunities for engagement with potential commercial partners

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

¹ To investigate the therapeutic potential for Xanamem to control the metabolic effects of excessive cortisol in a disease called Mild Autonomous Cortisol Secretion (MACS)

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

- Launched new corporate branding and logo. Launched new and enhanced corporate website

Intellectual Property

- Received *Grant of final composition of matter* patent for Xanamem from Brazilian Patent and Trademark Office which completes the global patent approvals for that patent family, granting composition of matter protection to 2031 and beyond in many countries
- Published provisional patent for scale up synthesis
- Submitted new provisional patent for treatment of Major Depressive Disorder.

Dr Steven Gourlay, Actinogen CEO and MD, commented:

"We continue to build momentum in our clinical development program after receiving positive results for improvement in attention and working memory in our XanaMIA Part A trial. We initiated a strategic adjustment to 'follow the science' by prioritizing our Alzheimer's Disease and Depression programs where the primary endpoints are cognition. We believe a focus on cognitive enhancement in these diseases will accelerate and optimize the path to commercialisation for our small molecule drug, Xanamem.®"

FY2022 Annual Report available today

Shareholders are encouraged to review the 2022 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 www.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 16 November 2022. The AGM will be in a 'hybrid' format this year that will allow for both in-person and virtual attendance and voting. Meeting time and details will be advised with the Notice of Meeting.

Statutory financial result

The statutory result for the 2022 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.³

The *Net after-tax loss* for the financial year ended 30 June 2022 was \$9,497,370 (FY21: loss of \$3,915,067).

The major expenditure item for the year was *Research and Development costs* of \$8,214,847 (FY21: \$2,406,237), primarily relating to clinical trials.

Financial position

At 30 June 2022, the Company had a *Cash and cash equivalents* balance of \$16,370,283 (30 June 2021: \$13,456,919), and *Net Assets* of \$21,739,877 (30 June 2021: \$17,458,081).

The cash balance of \$16.4 million at 30 June 2022 will be supplemented by an R&D tax incentive cash refund of \$3.6 million, expected before the end of calendar 2022.

³ The Company's third disease program for Fragile X Syndrome (FXS) is currently suspended pending the exploration of alternative funding, partnership and implementation models to study the utility of Xanamem in people living with FXS. The strong scientific rationale for the 11β-HSD1 enzyme as a therapeutic target has not changed.

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.

Based on the results of our trials conducted in more than 300 patients so far, the Company believes that it has the right team in place driving the right clinical strategy to create the greatest value from our highly promising drug.

Xanamem has the potential to be a first in class drug in the treatment of early stage Alzheimer's Disease and to be a first-in-class cognitive enhancer for Depression, with the added potential for being a successful anti-depressant (possible 'dual action').

We remain confident about our prospects in 2023 and beyond. We are now entering a valuable period of Phase 2 clinical data generation, with clinical data readouts for biomarkers in AD expected before the end of October 2022, the XanaCIDD Depression trial in late 2023 or 2024 and the XanaMIA Part B trial in early AD in 2024.

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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.

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 Xanamem has shown the ability to enhance cognition in healthy, older volunteers. 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. 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

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