**ASX ANNOUNCEMENT**

# Review of 2020 and outlook

**Sydney, 17 December 2020. Actinogen Medical ASX: ACW ('ACW' or 'the Company')** is pleased to provide investors with an end-of-year review and an outlook update, from Dr Bill Ketelbey, CEO and MD of Actinogen:

Dear Shareholders,

At this time of the year, it is tradition to reflect on the progress and achievements made this past year and to look forward to the exciting milestones in the coming year.

Actinogen is pleased with the many key milestones achieved in the 2020 calendar year. The Company has emerged from the global pandemic in a strong position despite the difficulties, and we continue to proactively manage our plans to build a clear pathway towards optimising future clinical trials and maximising value in the best interests of our shareholders. A summary of Actinogen's key milestones over the past year include:

- Completed a number of pre-clinical studies and progressed additional in vitro studies, which together with the existing clinical data, allowed a comprehensive analysis of the substantial Xanamem dataset. This will inform the next series of clinical trials.
- Selected Fragile X syndrome (FXS) as a new indication for Xanamem based on extensive scientific, clinical, and commercial review. Planning for the XanaFX trial – a phase II clinical trial to evaluate the safety and efficacy of Xanamem on anxiety, sleep and behavioural problems in adolescents with FXS, is progressing well.
- Finalised plans for XanaMIA – a phase II trial in mild cognitive impairment (MCI) due to Alzheimer's disease. This is the early stage of Alzheimer's disease and the study is designed to build on the positive Phase I XanaHES safety and efficacy results achieved last year.
- Successfully executed a capital raise to fully fund the XanaMIA and XanaFX phase II trials, which are expected to commence 1H CY2021.
- Business development activities continued throughout the year including numerous partnering meetings with prospective partners and presentations at virtual conferences including the AD/PD conference, ongoing grant submissions, publication preparation and the appointment of a CFO.

We look forward to building on the success of our previous Xanamem trials and the comprehensive analysis of the substantial clinical and preclinical datasets for Xanamem. This includes the breakthrough results from the XanaHES clinical trial announced late last year, that demonstrated a robust and statistically significant clinical effect on improving cognition in healthy elderly patients taking 20mg Xanamem daily. Additionally, the Phase I Target Occupancy study confirmed that Xanamem works as designed to penetrate the brain in concentrations that adequately inhibit the activity of the 11β-HSD1 enzyme, in the brain. These results have informed Actinogen's planning for further clinical development, including defining the key study parameters for phase II clinical trials in FXS and in MCI due to Alzheimer's disease. Additionally, we are planning studies in cognitive impairment associated with schizophrenia and diabetes and assessing other promising opportunities as they arise.

The Company is well positioned to progress further clinical development in the year ahead, following the successful placement and entitlement offer raising ~$7.4m. This capital raise fully funds the two upcoming phase II trials, XanaFX and XanaMIA. Additionally, an R&D tax incentive rebate of $2.9m was received for the 2020 financial year, further bolstering Actinogen's financial position. We are also pleased to welcome Mr. Jeff

Carter to the senior management team as Chief Financial Officer (CFO). With Actinogen's focus on progressing clinical development, Mr. Carter will provide robust, integrated and strategic financial support to the business.

During the year and following the unexpected external events of the global pandemic, Actinogen embraced the virtual environment to drive awareness among investor, academic and scientific communities. This includes presenting the latest Xanamem data at the AAT-AD/PD International Focus Meeting 2020, which took place virtually. Our continued participation in medical and scientific conferences, as well as partnering meetings and investor conferences, plays a pivotal role in driving awareness and building potential strategic opportunities for our clinical development.

The year ahead promises to be another year for the Company to achieve key milestones, with a strong capital position and significant groundwork now completed ahead of the new clinical trials. We look forward to commencing the new trials in 2021 and progressing the development of Xanamem. We are proud of the accomplishments achieved over the past calendar year and look forward to providing further positive and exciting updates for our shareholders, in the year ahead.

On behalf of the management team and Board, we wish you a safe and happy holiday season and thank you for your continued support and interest in Actinogen Medical.

Sincerely,

Bill Ketelbey
CEO & Managing Director

**ENDS**

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***Announcement authorised by the Board of Directors of Actinogen Medical***

**About Actinogen Medical**

Actinogen Medical (ASX:ACW) is an ASX-listed biotechnology company developing novel therapies for neurological, psychiatric and metabolic diseases associated with chronically elevated cortisol. The company is currently developing its lead compound, Xanamem, as a promising new therapy for Alzheimer's disease, Fragile X syndrome, schizophrenia and diabetes. The cognitive dysfunction, behavioural abnormalities, and neuropsychological burden associated with these conditions is significantly debilitating for patients, and there is a substantial unmet medical need for new and improved treatments.

**About Xanamem™**

Xanamem's novel mechanism of action works by blocking the production of intracellular cortisol – the stress hormone – through the inhibition of the 11β-HSD1 enzyme in the brain. There is a strong association between persistent stress and the production of excess cortisol that leads to detrimental changes in the brain, affecting memory, cognitive function and behaviour and neuropsychological symptoms. The 11β-HSD1 enzyme is particularly highly concentrated in the hippocampus and frontal cortex, areas of the brain impacted by a

number of diseases and disorders, including Alzheimer's disease, Fragile X syndrome, schizophrenia, diabetes and other conditions associated with chronically raised cortisol.

The Company's XanaHES Phase I trial exploring the safety and tolerability of Xanamem 20mg once daily in healthy elderly volunteers, confirmed the drug's safety profile with no treatment-related serious adverse events. Additionally, the trial demonstrated that Xanamem produced a statistically significant improvement in cognition over placebo, which, along with other recently generated data, confirms 11β-HSD1 inhibition by Xanamem as a promising potential treatment for cognitive impairment associated with raised cortisol.

The Company plans to initiate Phase II studies of Xanamem in various disease areas in 2021, including MCI due to Alzheimer's disease, and Fragile X syndrome.

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.

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**Actinogen Medical encourages all current investors to go paperless by registering their details with the designated registry service provider, Link Market Services.**