ASX ANNOUNCEMENT

Actinogen Medical FY21 Results – Progressing the Pipeline

Sydney, 30 August 2021. Actinogen Medical ASX: ACW ('ACW' or 'the Company') is pleased to release its results for the financial year ended 30 June 2021.

Key Highlights:

- **Demonstrated high levels of target occupancy in the brain for Xanamem daily doses ranging from 5mg to 30mg.** A relatively flat dose response curve across all doses supports the exploration of doses as low as 5mg in future studies.
- **Commenced XanaMIA Phase 2 study for Alzheimer's Disease.** The cognition data collected through the successful Phase 1 XanaHES trial in healthy older patients informs the two-part Phase 2 XanaMIA trial. Part A assesses the efficacy of 5mg and 10mg Xanamem doses compared to placebo. Part B will investigate the efficacy of Xanamem in patients with early-stage Alzheimer's Disease.
- **FDA granted Rare Paediatric Disease Designation (RPDD) for Xanamem in FXS.** RPDD provides for a faster, priority review of Xanamem for the FXS program and a second, transferable RPDD priority review voucher, if Xanamem is approved for FXS as its first indication. There are currently no treatments for FXS approved anywhere in the world.
- **Received positive XanaFX Phase 2 trial feedback from US FDA for Fragile X Syndrome.** Following a positive response to its pre–Investigational New Drug (IND) submission, ACW is preparing its full IND submission and its Phase 2 XanaFX trial, which is expected to commence in the second half of calendar 2021.
- **Appointed Corden Pharma as scale-up manufacturer.** Corden Pharma is a global pharmaceutical service and manufacturing platform that produces Active Pharmaceutical Ingredients (APIs), drug products, and provides associated packaging services. The Company appointed Corden to conduct the next stage of manufacturing for Xanamem.
- **Strengthened intellectual property (IP) portfolio.** ACW filed two patent applications for Xanamem to extend patent life protection until 2040.
- **Appointed highly credentialled CEO Dr Steven Gourlay.** Dr Gourlay has more than 30 years' experience in the development of novel small molecule therapeutics and brings extensive knowledge of the biotech industry to the senior management team.
- **Appointed key consultants to drive strategic projects.** Experienced strategic and technical consultants have joined the Company's team in key fields such as global regulatory affairs, clinical neurology, clinical pharmacology, biostatistics, pharmacology, toxicology, manufacturing, quality, and investor communications.
- **Secured new capital exceeding $10 million to fund clinical trials.** In October and November 2020, Actinogen raised $7.4 million to fund planned clinical trials and for general working capital. This included $6.0 million via an oversubscribed placement supported by new investors and existing shareholders, and $1.4 million under a non-renounceable 1 for 5 entitlement offer. A further $3.6 million was raised via a shortfall placement under the entitlement offer in February 2021.

CEO Commentary

Commenting on the FY21 result Actinogen CEO, Dr Steven Gourlay, said:

"Despite challenging global circumstances, Actinogen has continued to execute its strategy which consists of a 'Fast-to-Market' approach with Fragile X Syndrome, a 'Big-to-Market' approach with Alzheimer's Disease and planning additional diversification with a third disease program."

We met significant milestones this year including the initiation of our Phase 2 XanaMIA trial, positive pre-Investigational New Drug (IND) feedback from the US FDA for our XanaFX trial and Rare Paediatric Disease Designation for the Fragile X program."

We will continue to follow the science to optimise the clinical development pipeline that is designed to deliver 'multiple shots on goal' with timely and high-quality confirmation of clinical efficacy and safety in each of our disease programs."

Actinogen, through its lead drug Xanamem, is at an exciting stage of development and poised to deliver valuable new clinical data in 2022 and 2023. The impact of our programs could be life-changing for many patients and their families."

Statutory Result

The statutory result for Actinogen for the 2021 financial year reflects the Company's ongoing investment in developing and advancing its lead molecule Xanamem for the treatment of Alzheimer's Disease and Fragile X Syndrome, along with exploring and enhancing relationships with potential future development partners.

Financial Performance

The net after-tax loss for the year to 30 June 2021 was $3,915,067 (FY20: loss of $5,330,529).

The major other income item during the year was an R&D tax rebate of $1,438,571 (FY20: $3,315,125), while the major expenditure item was R&D costs of $2,406,237 (FY20: 5,537,170) in relation to clinical trials.

Financial Position

At 30 June 2021 the Company had a cash and cash equivalents balance of $13,421,653 (30 June 2020: $5,040,486), and Net Assets of $17,458,081 (30 June 2020: 10,888,505).

Strategy and Outlook

Actinogen remains well funded with a strong cash balance of $13.4 million as at 30 June 2021, sufficient to fund all planned phase 2 clinical trials. The cash balance will be supplemented by an R&D tax incentive cash refund of approximately $1.4 million expected by the end of calendar 2021.

The Company has been fortunate to continue its programs without significant delays despite the Covid-19 pandemic and its associated lockdowns. We continue to manage our clinical programs with risk mitigation for future Covid-19 developments but anticipate some impact on trial enrolment will be experienced.

The Company's three strategic priorities are:

1. Operational excellence to deliver high quality, timely clinical data in 2022 and 2023
2. Strengthening strategic and expert partnerships
3. Forward Planning to optimise timelines to marketing approval(s)

Actinogen is focused on excellent clinical development, designed to deliver 'multiple shots on goal' with timely and high-quality confirmation of clinical efficacy and safety in each of its disease programs. The Company is conducting its lead programs under a US Investigational New Drug (IND) process to ensure that the highest standards of regulatory compliance are are achieved.

Part A of the XanaMIA study is expected to read out in H1 CY22 and Part B approximately a year later in 2023. The Fragile X trial will commence later in calendar 2021, with a read out in 2023. A carefully chosen third indication, will commence in 2022.

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 diseases associated with dysregulated brain cortisol. The Company is currently developing its lead compound, Xanamem™, as a promising new therapy for Alzheimer's Disease, Fragile X syndrome, and other potential neurological diseases. 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 Company has studied 11β-HSD1 inhibition by Xanamem in more than 200 volunteers and patients, finding a statistically significant improvement in cognition over placebo in healthy, older volunteers. A series of Phase II studies in multiple indications will be conducted to further confirm and characterise Xanamem's efficacy and safety.

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, Automic Group.