



## **Actinogen Medical Annual General Meeting 12<sup>th</sup> November 2015**

### **Martin Rogers, Chairman, Actinogen Medical**

Welcome to the 2015 Annual General Meeting of Actinogen Limited. Your Directors are here today including your Chief Executive Officer Dr Bill Ketelbey with an apology from Dr Jason Loveridge who is currently overseas.

I would like to begin by noting some changes to your Board over the past year. First, it is my pleasure to welcome Dr Bill Ketelbey and Dr Jason Loveridge. Bill has over extensive experience in the pharmaceutical sector including senior executive roles as Vice-President for the Asia-Pac region and Country Medical Director for Pfizer in Australia and New Zealand. Jason has been working in the biotechnology space for over 25 years and brings extensive experience in commercialisation of medical research including as a Director at JAFCO Nomura's life sciences business.

I would also like to recognise the contribution of Dr Brendan de Kauwe and Mr Daniel Parasiliti. Brendan and Daniel on behalf of the Board and shareholders, thank you for the significant role you have played with the transition of the new assets.

### **New Focus on Alzheimer's Dementia Drug Development**

I am excited to speak with investors today given our new commercial focus on treating Alzheimer's disease following the acquisition of the novel drug Xanamem™ on 1<sup>st</sup> December last year.

Xanamem™ represents an historical new approach to treating Alzheimer's disease – a condition with a significant unmet medical need that threatens to place a huge burden on society. It works by blocking the development and regeneration of cortisol – the "stress hormone" – which appears to contribute to the cognitive impairment, amyloid plaques and neural death associated with Alzheimer's disease.

Your Board of Actinogen Medical was attracted to Xanamem™ for several reasons:

- This new approach to treating Alzheimer's is backed by pre-clinical and clinical data supporting the novel mechanism of action around suppression of the "stress hormone" cortisol.
- Early development of Xanamem™ was supported by the medical research charity The Wellcome Trust which invested \$25 million over seven years on product development.
- This combined with the successful completion of the first Phase 1 trial, is excellent validation for an asset at this stage of development.

- Further independent validation comes from the respected financial information organization, Thomson Reuters, which recently rated Xanamem™ (UE2343) as one of the top-five drugs in Phase 1 development in the global pharmaceutical or biotech industries.

Alzheimer's disease is one of the most common forms of dementia and has a debilitating effect on patients and their loved ones. Alzheimer's is also growing rapidly: the American Alzheimer's Association estimated that the healthcare cost of the disease was \$US250 billion in 2013, and by 2050, the cost of care for people with the disease in the US alone is expected to be \$US1.08 trillion, outstripping the cost of treating all other diseases.

While there are four different drugs on the market they only treat the symptoms of Alzheimer's to some degree. **There are currently no drugs that can significantly alter the course of the disease and one is badly needed.** With the development of Xanamem™, we are hopeful of finding an effective treatment for Alzheimer's disease in its earlier stages, when patients first start to demonstrate early symptoms of the disease.

### **Appointment of Clinical Advisors**

This year your Company has appointed a group of world leading Alzheimer's specialists with particular expertise in early diagnosis and treatment of Alzheimer's disease. The members include

- Professor Craig Ritchie, Professor of Psychiatry of Ageing at the University of Edinburgh
- Professor Colin Masters, Executive Director of the Mental Health Research Institute and Laureate Professor at the University of Melbourne
- Professor Jeff Cummings, Camille and Larry Chair of the Neurological Institute of Cleveland Clinic and Professor of Medicine(Neurology)

They have already this year helped Actinogen Medical shape the research and drive the development of its new lead research drug, Xanamem™

### **Phase 1 Successfully Complete with Positive Results**

It is pleasing to highlight the Phase I is successfully complete with positive results. In particular, the much anticipated recent results from the final Phase I clinical trial confirm that Xanamem™ crosses the blood-brain-barrier and is effectively delivered to the brain, its primary site of action in Alzheimer's disease.

These results are particularly encouraging as they confirm that following oral administration, Xanamem™, reaches the brain in concentrations that are predicted to very effectively inhibit the 11beta-HSD1 enzyme in the brain.

These results followed on from the earlier Phase I results that demonstrated the safety and tolerability of Xanamem™, even at the highest dose of 35mg twice daily. These data will be used to define the optimum daily dose for Xanamem to take forward into the Phase II clinical trial. The total participants in Phase I studies was n=88.

The unique mechanism of action around cortisol inhibition and the validation that the drug clinically crosses the blood-brain-barrier are critical for the confidence we have advancing in this program.

### **Capital Raising**

To ensure Actinogen Medical has sufficient capital to undertake the next level of commercialisation research, the Capital Raising in May 2015 successfully raised adequate funds to run the study and cover corporate expenses through to the end of the Phase II study, currently envisaged to complete around the end of 2017.

## **Phase II Study to Start Recruitment in 2016**

Following on from the Phase I successful completion with position results; the next major step is in initiating the Phase II study in Alzheimer's disease. This is on-time and on-budget to inform the design and regulatory approvals for the Phase II study, planned for initiation in the first half of 2016. The Clinical Advisory Board have been convened with appropriately experienced global experts to help design the optimum Phase II protocol, and commercial Regulatory and Research partners have been contracted to assist with the regulatory and research logistics of ensuring we are undertaking GCP and Regulatory complaint quality research. We have additionally contracted a specialist API manufacturer in the UK to make a batch of active drug for the study.

All these initiatives are on track to deliver a Phase II study, and the Company expects to be able to start treating Alzheimer's patients in the trial in the first half of 2016. The trial will treat around n=200 patients in Australia, the UK and the USA, under an U.S. Food & Drug Administration (FDA) approved Investigational New Drug (IND).

## **Outlook**

Concurrently to initiating the Alzheimer's Phase II study, development of some additional clinical indications for Xanamem™ that are evident through the underlying mechanism of action (inhibition of cortisol production) are to be evaluated. These include a number of commercially promising Central Nervous System (CNS) indications such as Post Traumatic Stress Disorder (PTSD), cognitive decline in depression and schizophrenia and Parkinson's disease.

Earlier in the year I was present at a number of meetings between the Company's senior management and pharmaceutical companies who have existing or potential interest in the Alzheimer's dementia market. The genuine interest in our Xanamem™ program from multiple parties was quite obvious. We have every reason to be confident that a good result from the current trial should result in a competitive and rewarding partnering process on the completion of this study.

## **Conclusion**

In this period we have acquired and are underway in developing one of the most promising assets in Alzheimer's dementia.

However, the best asset by itself is no guarantee of long-term success.

We have a world class management team and clinical advisors headed by Bill. Together, they lead a team of hardworking, well trained and dedicated people. All of them have a clear sense of purpose and are guided by a clear set of values to help drive the commercialisation of research behind Xanamem™ for those suffering from the dreaded disease of Alzheimer's dementia.

On your behalf, I thank all of our team and thank you for your continued support.

*The Chairman then conducted the formal items of business*