

27 November 2020

ACW 2020 AGM Chairman's address

Good morning,

My name is Geoff Brooke, and I am the Chairman of Actinogen. It is my pleasure to welcome you all to Actinogen Medical Ltd's 2020 Annual General Meeting.

With me today I have members of the Actinogen board and management. We have our CEO and MD, Dr Bill Ketelbey, who will address you shortly, as well as non-executive directors Dr George Morstyn and Malcolm McComas. Also present from the Company is Tamara Miller, our VP of Drug Development and Strategy. I would also like to acknowledge our newly appointed Chief Financial Officer, Jeff Carter; as well as Company Secretary, Peter Webse, and Pierre Dreyer who is representing Ernst & Young, the Company's auditor.

With the onset of a global pandemic earlier this calendar year, the challenges faced by the world have in many ways been unprecedented. Throughout the health crisis, our primary focus has been on taking the necessary health and safety precautions to protect our staff, collaborators, study participants and the broader community. Fortunately, our ongoing studies have largely been completed, ensuring we can now focus on data analysis and planning for future trials. Hence the direct impact the pandemic has had on us has been being fairly limited to date. Actinogen has emerged from the pandemic in a strong position and we continue to proactively manage our operations and clinical development plans, in order to build a clear pathway towards optimising future clinical trials and maximising value in the best interests of our shareholders.

Late last year, Actinogen achieved a breakthrough with the XanaHES clinical trial. The results from this trial demonstrated a significant improvement in cognition in healthy elderly patients dosed with Xanamem 20mg daily for 12 weeks. This marks the first time that Xanamem, or any brain-penetrant 11B-HSD1 inhibitor, has exhibited such a clear and statistically significant cognitive improvement in human trials, while demonstrating that the 20mg dose is safe and that it effectively inhibits cortisol production. Further support for the successful development of Xanamem was subsequently demonstrated in the Target Occupancy Study, where the study demonstrated that Xanamem works as designed, by crossing the blood-brain-barrier and effectively binding to the target 11 β -HSD1 enzyme in the brain.

These results, alongside those from the XanaHES and XanADu trials that demonstrated that Xanamem suppresses cortisol production and improves cognition, are ground-breaking, as they confirm Xanamem's proof-of-concept, as well as the whole principle that underpins the development of Xanamem. These results reinforce the significant potential in developing Xanamem for a number of conditions presenting with raised cortisol and cognitive impairment, including Alzheimer's disease.

Leveraging the success of the XanaHES trial and comprehensive analysis of the substantial clinical and pre-clinical data set of Xanamem, Actinogen has been able to define the key study parameters for a Phase II clinical trial in Mild Cognitive Impairment (MCI) due to Alzheimer's disease. This is a patient population where the disease has only just been diagnosed and where there is the best opportunity for achieving a response to treatment. Importantly, this study will link the compelling XanaHES trial results with an Alzheimer's disease population, supporting our expectation that we will see a similarly strong result as we saw with XanaHES. Alzheimer's disease and MCI represent a huge unmet medical need and a substantial market opportunity, with no therapeutic options currently available in the market.

A detailed and comprehensive review of academic and scientific research supports exploring applications in human disease focusing on cortisol inhibition. Actinogen continues to drive ongoing development of Xanamem across a number of indications and with the strategy to broaden the development pipeline for Xanamem. This includes the recently announced fully funded Phase II clinical trial to evaluate the safety and efficacy of Xanamem on anxiety, sleep and behavioural problems in adolescent males with Fragile X syndrome (FXS).

Additionally, we are planning studies in cognitive impairment associated with schizophrenia and diabetes, and assessing other promising opportunities as they arise.

While the ongoing pandemic has caused disruption across our industry, we remain confident in our ability to navigate these challenges. Actinogen has embraced the virtual environment and continues to drive awareness among investor, academic and scientific communities. This includes presenting latest Xanamem data at the AAT-AD/PD International Focus Meeting 2020. Our continued participation in medical and scientific conferences, as well as partnering meetings and investor conferences, plays a pivotal role in driving awareness and builds potential strategic opportunities for our clinical development. With a strong capital position, following the completion of the recent capital raising, and significant groundwork completed ahead of our new clinical trials, we look forward to commencing the new clinical trials in 2021 and rapidly progressing the development of Xanamem.

Lastly, we were very pleased to be able to undertake a placement and rights issue, where we raised a total of \$7.4M to essentially fund the XanaMIA clinical trial. The board would like to express thanks to those institutions and individual investors who participated, and we hope the investment delivers significant return for shareholders.

Before I pass over to Bill for the CEO presentation, I would like to take this opportunity to thank all our Actinogen's shareholders, for their continued support of the Company's endeavours. I would also like to thank our staff and partners for their ongoing hard work and dedication my fellow Board members for their commitment to Actinogen. I will now handover to Dr Bill Ketelbey, our CEO and Managing Director, to provide an update on Actinogen's clinical development programs and outlook.

ENDS


Actinogen Medical

Dr. Bill Ketelbey

CEO & Managing Director

P: +61 2 8964 7401

E: bill.ketelbey@actinogen.com.au

 @BillKetelbey

Investor Enquiries

Miranda Newnham

Vesparum Capital

P: +61 3 8582 4800

E: actinogen@vesparum.com

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 11 β -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 11 β -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 11 β -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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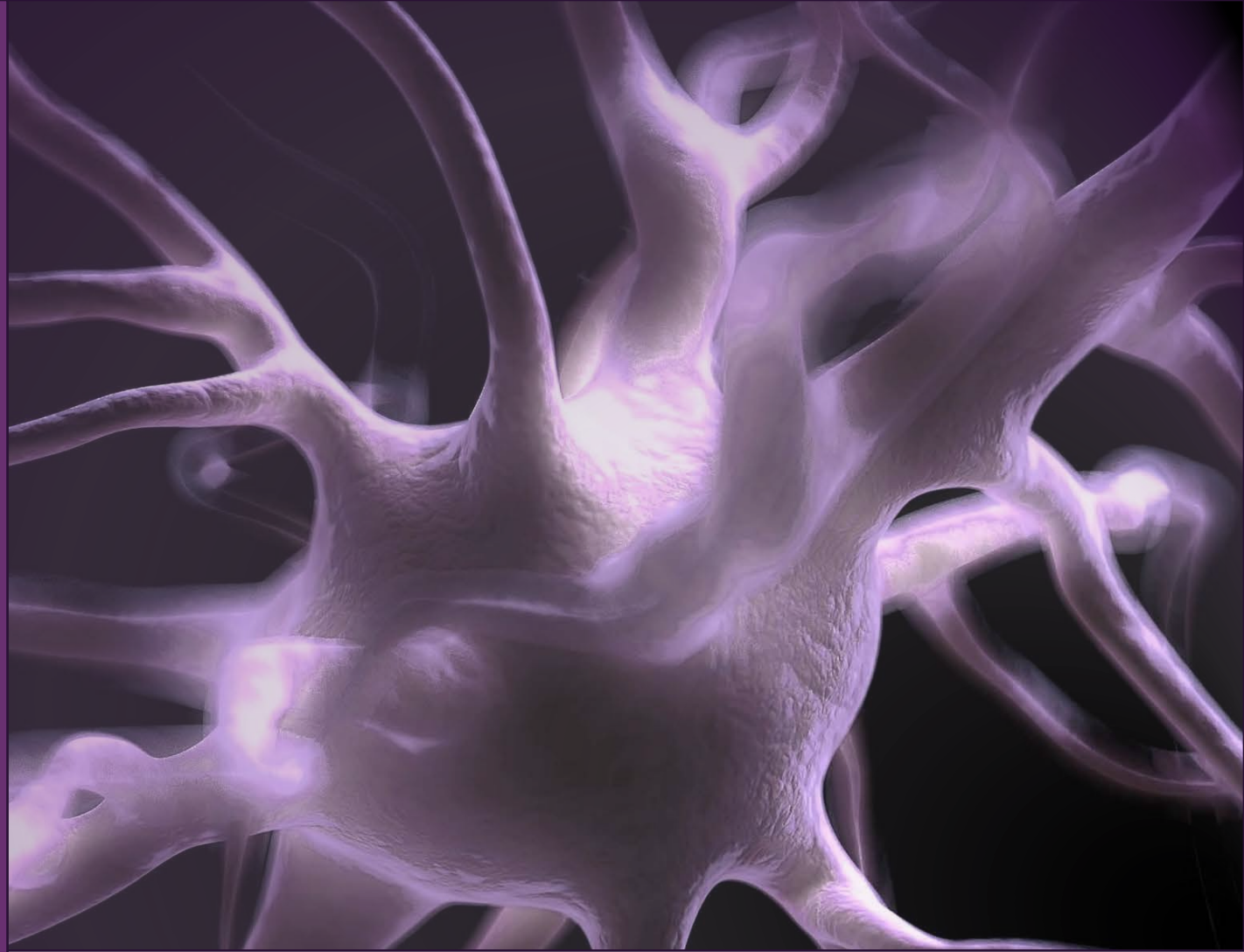
Actinogen Medical encourages all current investors to go paperless by registering their details with the designated registry service provider, Link Market Services.

AGM Presentation

Dr. Bill Ketelbey: CEO & MD

27 November 2020

Developing novel therapies for cognitive impairment and behavioural symptoms due to raised cortisol in chronic neurological, psychiatric, developmental and metabolic diseases



YEAR IN REVIEW

October 2019

XanaHES results: breakthrough cognitive efficacy

February - April 2020

Target Occupancy data: supports Xanamem works as designed

April 2020

Preparation ramps up for XanaMIA and XanaFX studies

September 2020

Comprehensive analysis of dataset complete

October 2019 - October 2020

Manufacturing optimisation: enhancing Xanamem synthesis

October 2020

Raised capital to fully fund two upcoming phase II trials

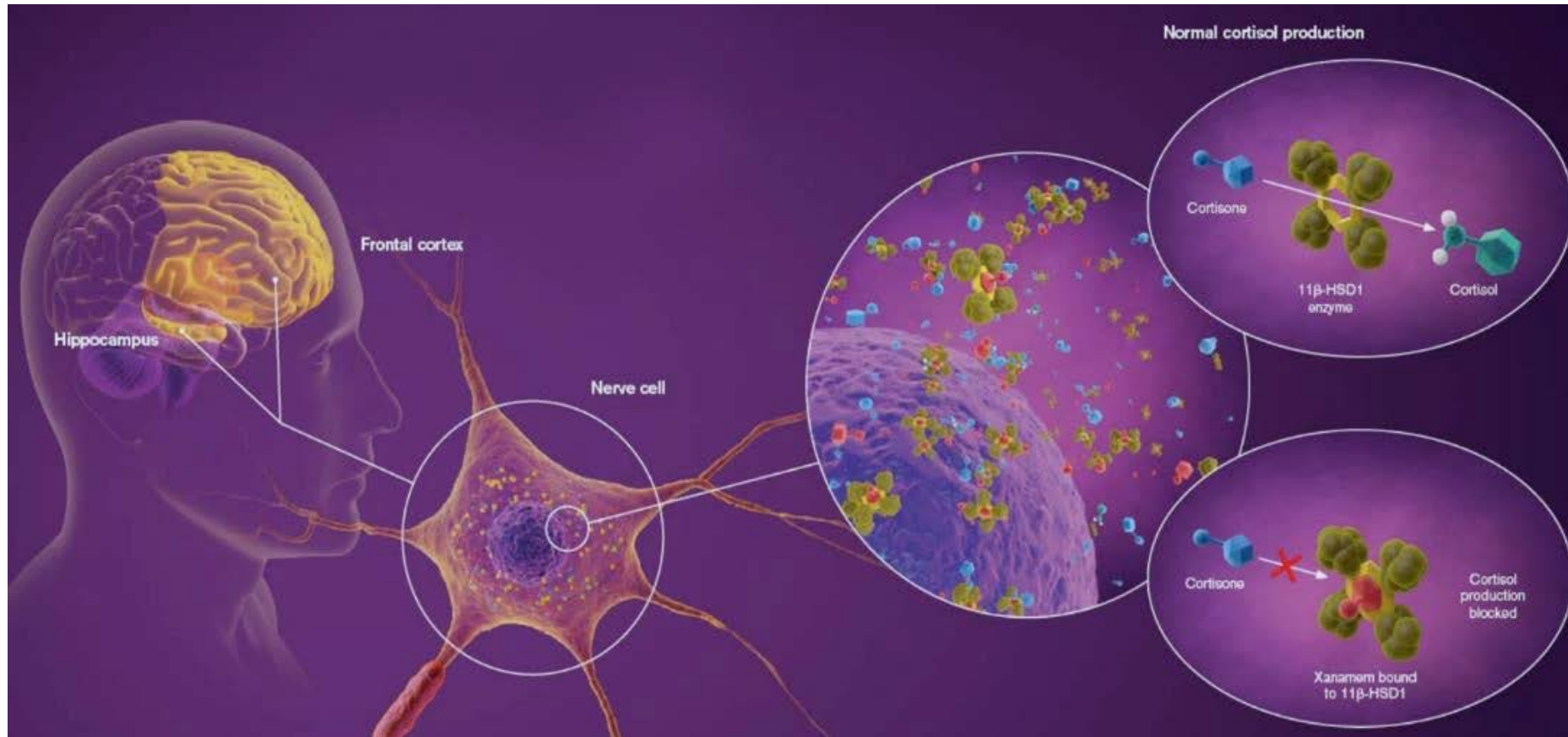
November 2020

Strengthening IP protection with two new patents filed



Xanamem™ - lead compound

Novel Mechanism of Action - designed to inhibit cortisol production in the brain (through inhibition of the 11 β -HSD1 enzyme)



Compelling results from various studies underpin further clinical development



Pre-clinical long-term toxicology studies



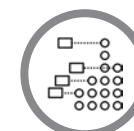
Phase II trial in Alzheimer's patients (10mg daily)



Phase I Target occupancy & Homogenate binding



Phase I trial in Healthy Elderly Subjects (20mg daily)



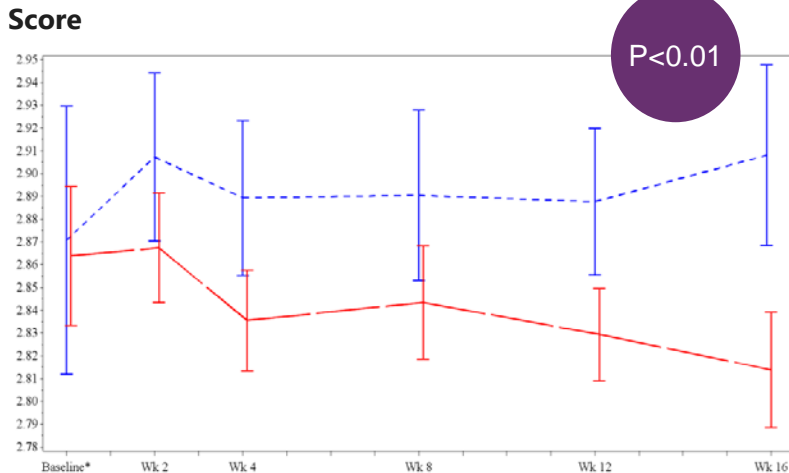
Comprehensive dataset analysis

Significant cognitive efficacy signal achieved

Breakthrough XanaHES results¹ demonstrate robust statistically significant cognitive efficacy improvement in multiple cognition domains – based on Cogstate Cognitive Test Battery

Working memory (One Back Test)

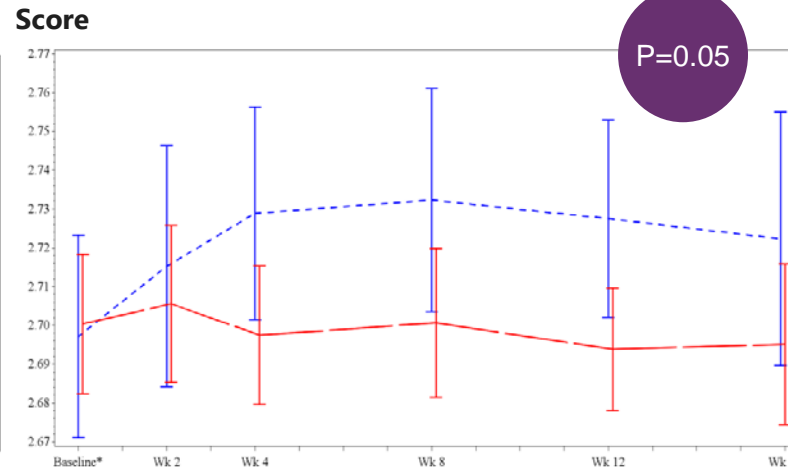
Strongly statistically significant result



Rapid response, evident by week 4, and sustained response out to end of therapy (wk 12)

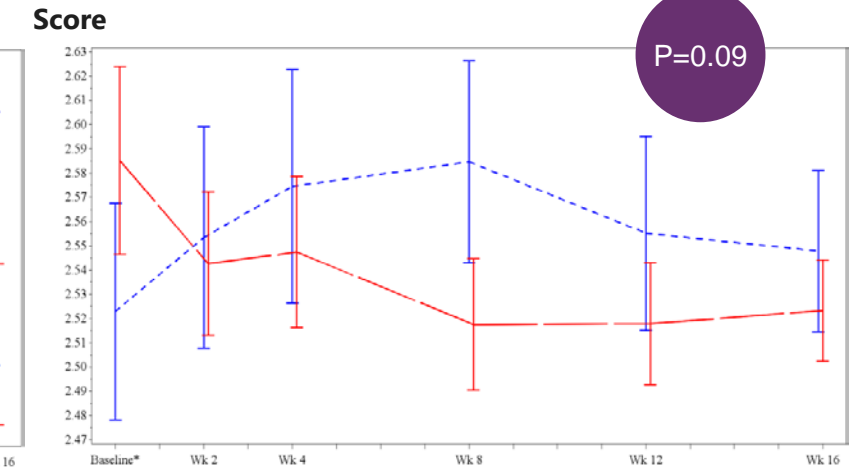
Visual attention (Identification Test)

Statistically significant result



Psychomotor function (Detection Test)

Good trend to a positive result



Treatment Group

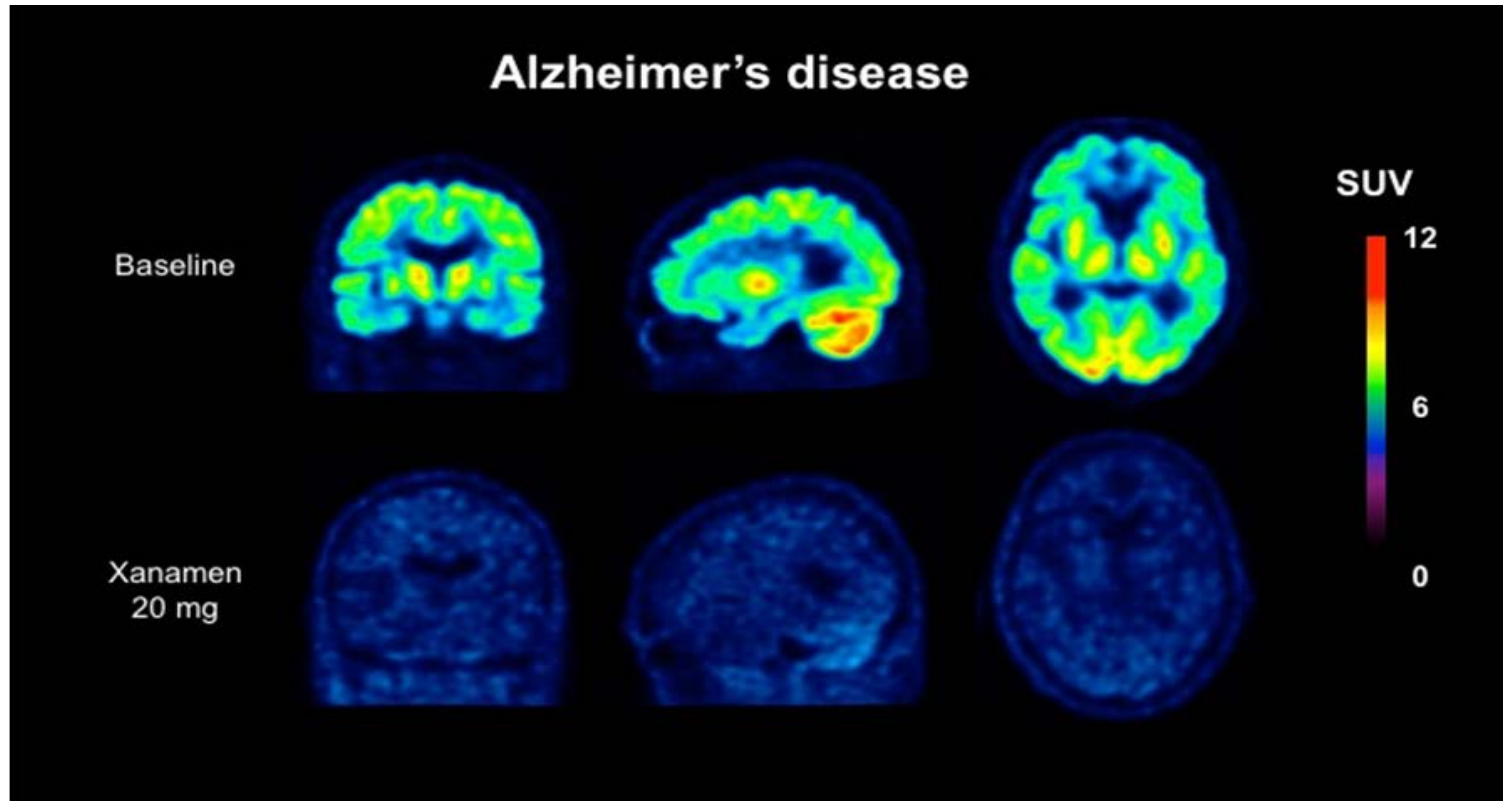
— Xanamem 30pts — Placebo 12 pts

Efficacy results reflect high quality and consistent data in a small study population



Target Occupancy study: positive confirmatory data

Phase I target occupancy study demonstrates that 5mg to 30mg Xanamen dosed for seven days significantly binds to the neuronal 11 β -HSD1 enzyme throughout the brain (32 of 36 patients completed)







**50% to 85% occupancy,
dependent upon brain
region, dosage and
study subject¹**

Phase I Target Occupancy supports Xanamen as a potent, orally bioavailable and brain-penetrant 11 β -HSD1 inhibitor

Key outcomes from Xanamem studies

Xanamem, an oral compound, demonstrated to be an efficacious, safe, brain penetrant, selective and effective 11 β -HSD1 inhibitor producing significant pharmacodynamic effects on cortisol

<i>Xanamem dose</i>		
 Cognitive Efficacy	Breakthrough results demonstrate a statistically significant clinical effect in improving cognition in healthy elderly patients	20mg
 Target Occupancy	Confirms Xanamem works as designed to penetrate the brain in concentrations that adequately inhibit the activity of 11 β -HSD1 enzyme	5mg - 30mg
 Cortisol inhibition	Cortisol inhibition demonstrated pharmacodynamically in human trials	10mg & 20mg
	Statistically significant reduction in serum cortisol in human trial	20mg
 Safety	Strong safety profile demonstrated in human trials	10mg & 20mg

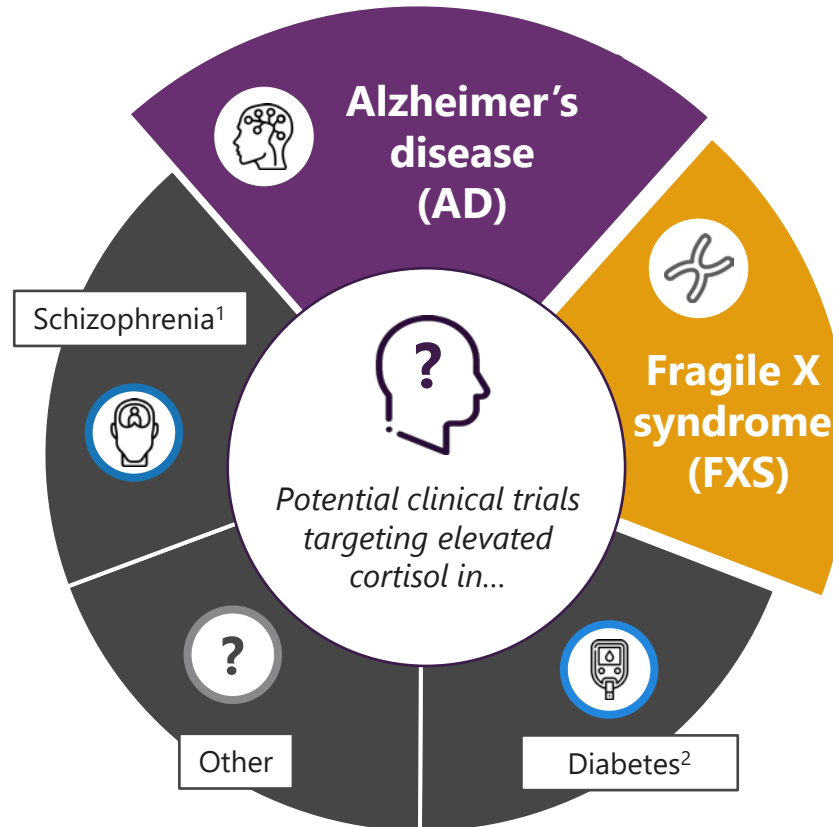
Leveraging clinical development across multiple indications

Two fully funded phase II trials to commence 1H CY21



Continued focus on Alzheimer's disease

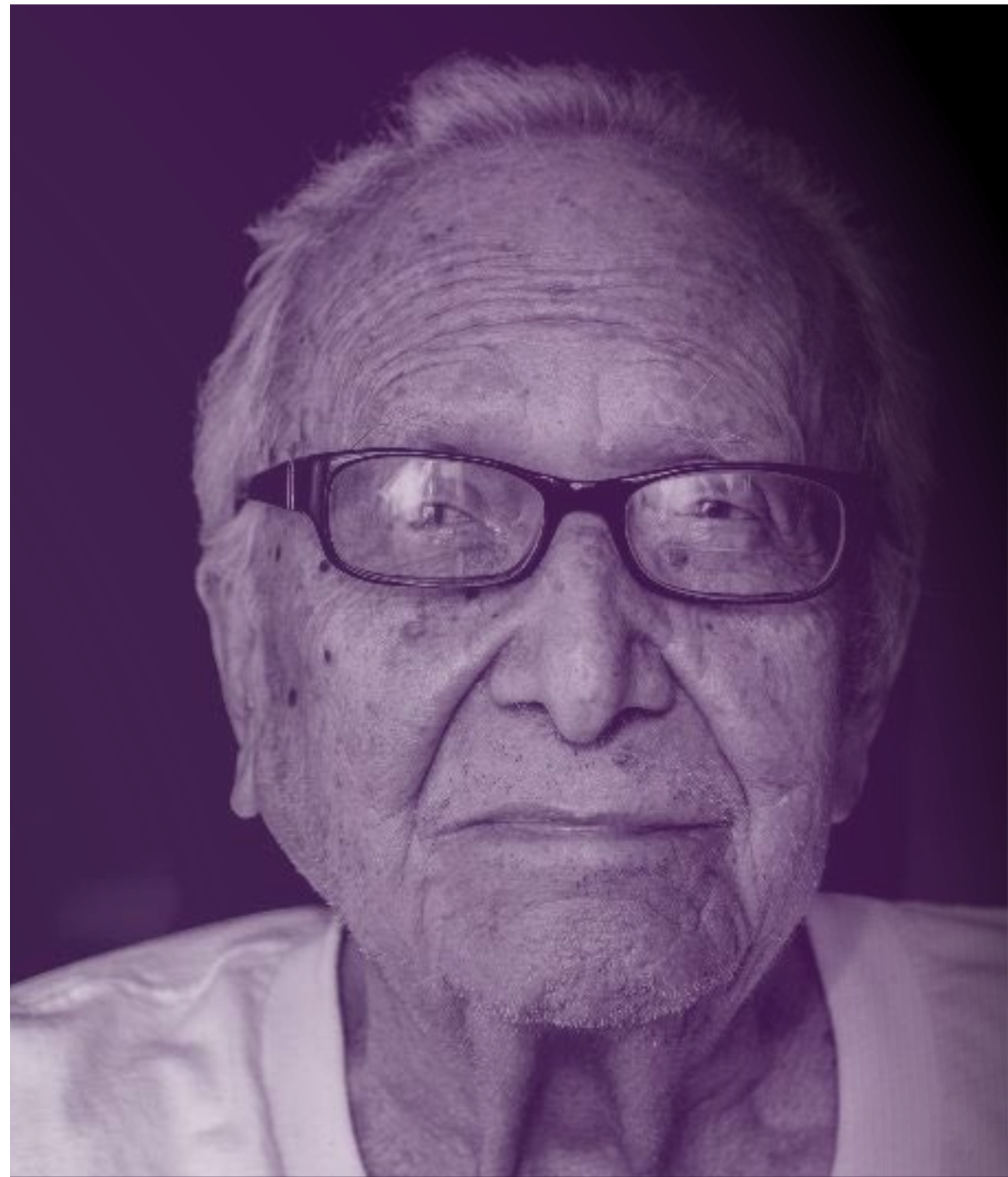
XanaMIA: Fully funded phase II trial in patients with mild cognitive impairment due to Alzheimer's disease



FXS selected as next clinical development opportunity

XanaFX: Fully funded phase II trial targeting anxiety, sleep, and behavioural problems in FXS patients

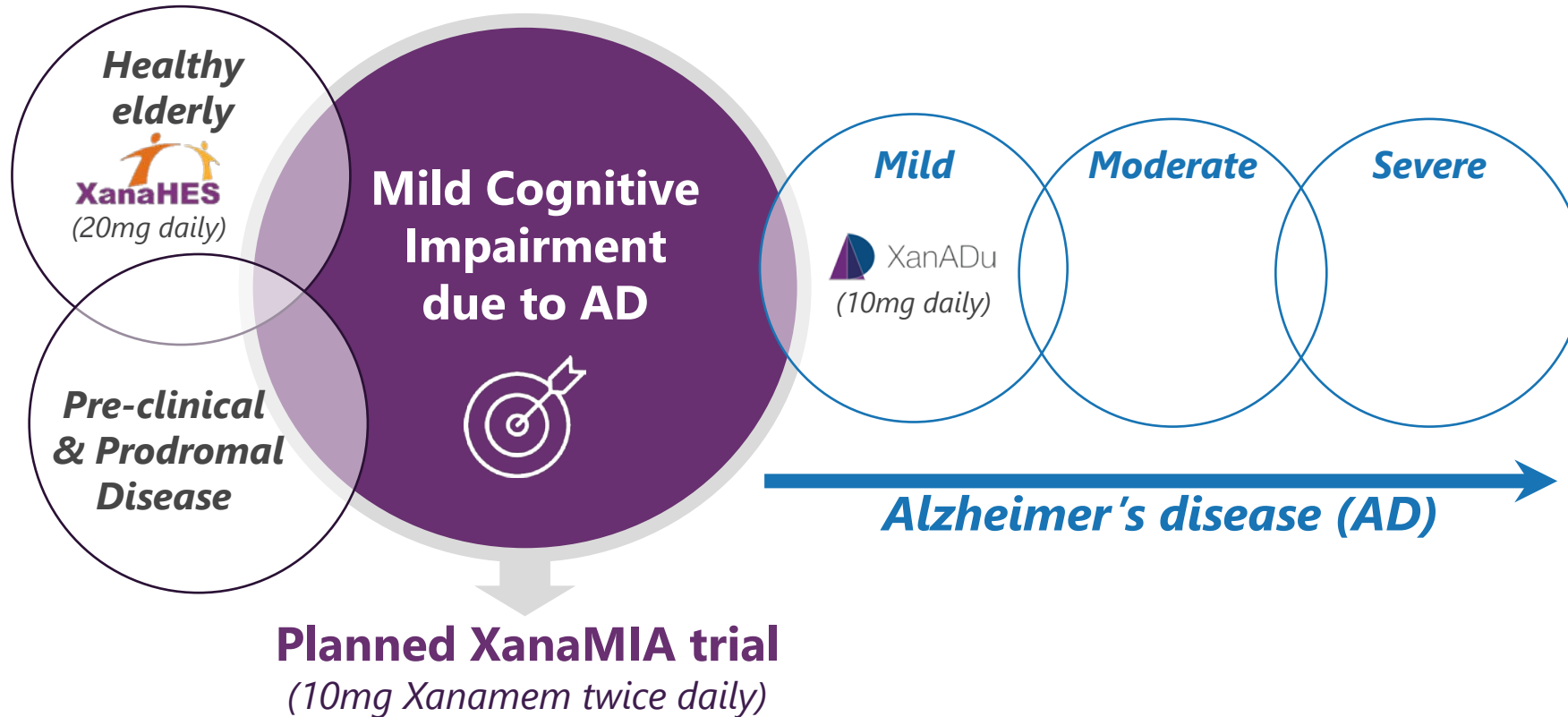
Mild cognitive impairment
due to
Alzheimer's disease





Alzheimer's disease - Mild Cognitive Impairment due to AD

XanaMIA - evaluating Xanamem in patients with Mild Cognitive Impairment (MCI) due to AD (an early stage of the AD spectrum), linking the compelling XanaHES results with an Alzheimer's disease patient population



- MCI due to Alzheimer's affects **~8% of those over 65 years of age**
- **Conversion rate** to mild Alzheimer's **~10-15% per annum**
- Patients have characteristic **patho-physiological changes of Alzheimer's** (ie. functional impairment)



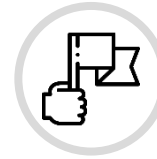
XanaMIA - Phase II clinical trial

Phase II trial to demonstrate the safety, tolerability and efficacy of Xanamem in patients with MCI due to AD

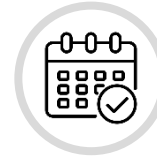
Key design learnings incorporated into XanaMIA

- Enriched eligibility criteria including biomarkers
 - 72 males & females (65-80yrs) with MCI due to AD
 - 24 weeks treatment; clinical sites in Australia
 - 10mg twice daily dose
 - Numerous cognitive endpoints including Cogstate NTB from XanaHES
 - Numerous objective biomarker endpoints
-

Key milestones



Commence recruitment in 1H CY21¹



Expected **completion within 24 months¹**



Trial fully funded



Alzheimer's disease remains a focus

Market dynamics of Alzheimer's disease presents a compelling commercial opportunity for Actinogen

Substantial target market with significant upside¹

Cognitively normal	Subjective memory decline	Cognitive and functional decline fulfilling Alzheimer's disease (AD)		
At-risk	MCI due to AD	Mild	Moderate	Severe
15.5m ³ -26.9m ⁴	~4.3m	~1.7m	~2.3m	~1.7m

Upside potential for earlier use

Key focus

> US\$13.7bn

Target annual peak sales²

Underpinned by favourable market dynamics



Targeting **large addressable** markets (US, EU5⁵, JP)

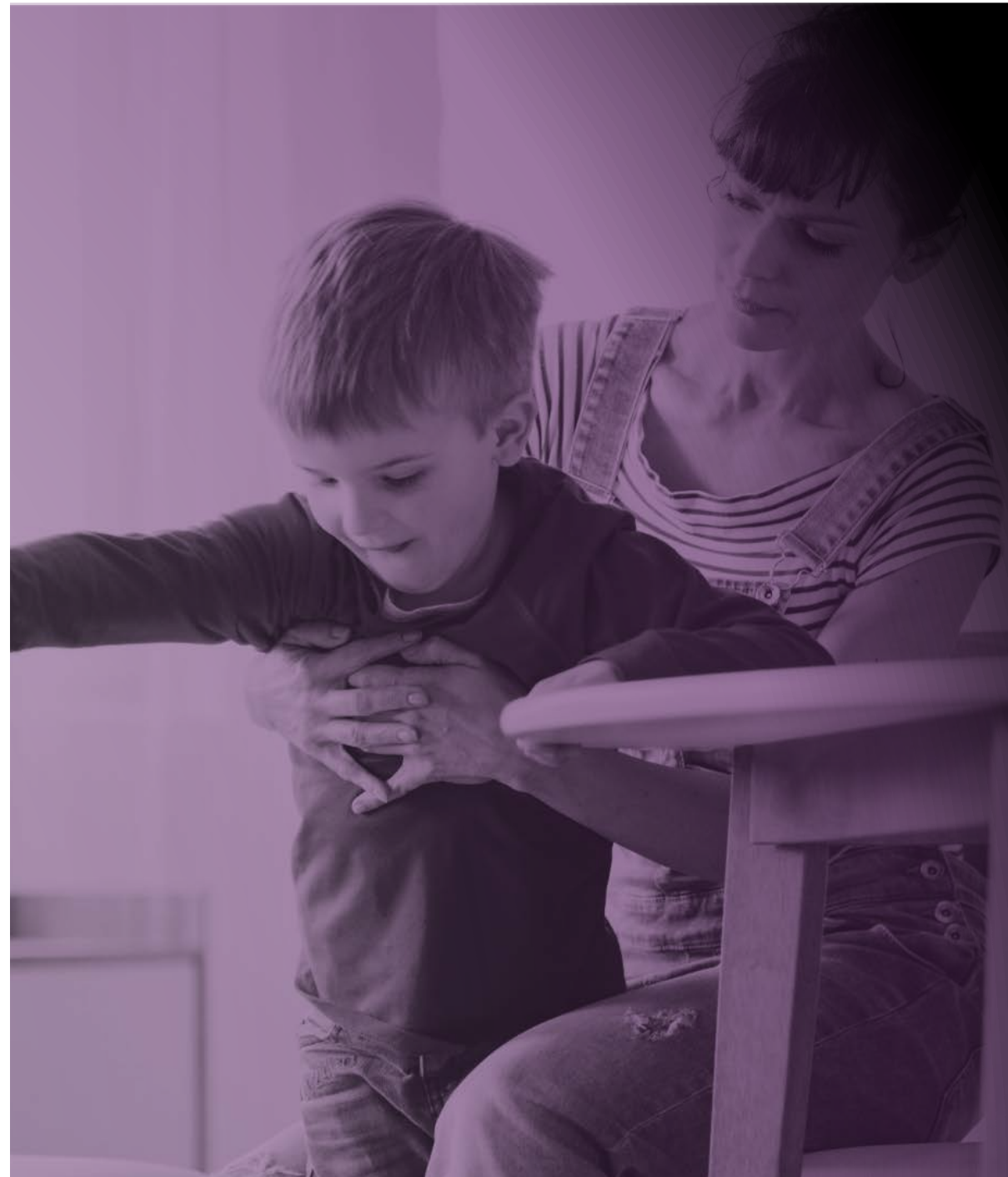


All **currently approved drugs are symptomatic treatments** (that do not affect disease progression) **providing limited benefit**



Treatment **prices are robust** (despite generic competition) – with users paying for modest clinical efficacy

Fragile X syndrome





Anxiety, behavioural problems and sleep in Fragile X syndrome

FXS is a rare genetic condition representing a significant unmet medical need

FXS is characterised by a range of developmental problems, including:



Cognitive impairment



Anxiety¹



Speech and language deficits



Behaviour problems



Sleep problems



Learning disabilities

Behavioural, anxiety and cognitive problems in FXS is often **associated with raised cortisol**; **Xanamem has potential as a treatment for these debilitating symptoms**



Actinogen has selected anxiety, behavioural problems and sleep in FXS as an additional clinical development opportunity

Unmet medical need

*Management of FXS is often complex, with life-long treatment required for patients - **there are no approved drugs to treat FXS***

Strategic benefits

*Xanamem in FXS potentially eligible for **Orphan Drug and Rare Paediatric Disease Designations**, providing attractive regulatory, development, and commercial benefits*

Data generation

*Data generated could be **leveraged for other indications** and presents a significant potential upside with FXS-related condition, such as Autism Spectrum Disorder*



Valuable FXS market opportunity

While FXS is a rare disease, anxiety, sleep, and behavioural symptoms in FXS represent substantial commercial opportunities

Target population

*Anxiety, sleep, and
behavioural problems
in FXS adolescents*

Prevalence

*Approx. 1 in 2500-4000 males
and 1 in 7000-8000 females
(averages to 1/4500)*

**Substantial market
opportunity¹**

~US\$250m
With 14.4% compound annual growth

XanaFX - Phase II clinical trial

Phase II trial to demonstrate the safety and efficacy of Xanamem on anxiety, sleep, and behavioural problems in patients with Fragile X syndrome

Proposed clinical trial design

- Proof-of-concept study
 - Double-blind, placebo-controlled
 - Investigator-Initiated Trial, conducted with Murdoch Children's Research Institute
 - Planning for ~40 adolescents (12-18yrs) with FXS
 - Evaluating safety and efficacy of Xanamem on anxiety, sleep and behavioural problems in patients with FXS
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Key upcoming milestones



Planned to **commence recruitment in 1H CY21¹**



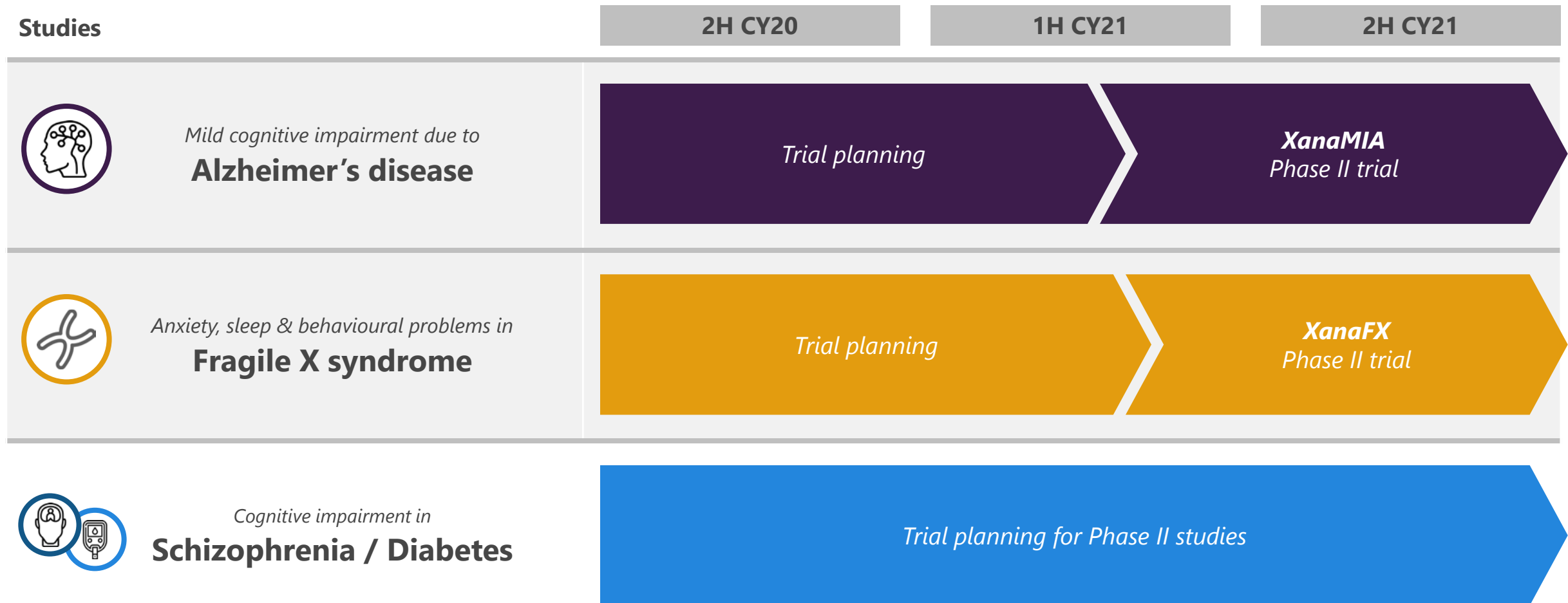
Expected **completion within 12 months¹**



Trial **fully funded**

Attractive development pipeline

Targeting a broad portfolio of clinical indications to assess the efficacy of Xanamem



Next steps and key catalysts

Plans for key clinical trials to commence in 1H CY21

- ❑ **Finalise optimal study parameters and trial protocols** (4Q CY20)
- ❑ **Receive ethics and regulatory approval and commence next phase of clinical trials – XanaMIA / XanaFX** (1H CY21)
- ❑ **Completion of Target Occupancy study** (1H CY21)
- ❑ **XanaFX study readout** (12 months from trial commencement)
- **Potential for FXS Orphan Drug and Rare Paediatric Disease Designations**
- **Submit additional grant applications** and explore potential funding opportunities with external partners
- **Publications** on existing results and new indications providing important validation of Xanamem's mechanism of action and raising awareness of Xanamem's broad potential



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