



ASX ANNOUNCEMENT

Actinogen to present at ShareCafe Small Cap Webinar

Sydney, 4 August 2021. Actinogen Medical ASX: ACW ('Actinogen' or 'the Company') is pleased to announce its participation in the ShareCafe Small Cap "Hidden Gems" Webinar, to be held Friday 6th of August 2021 from 12:30pm AEST / 10:30am AWST.

Actinogen CEO and Managing Director Dr. Steven Gourlay will provide an overview of the Company's novel therapy for neurological diseases associated with dysregulated brain cortisol, the once daily oral medication Xanamem™, a promising new therapy for Alzheimer's Disease, Fragile X syndrome, and other neurological diseases.

This webinar is able to be viewed live via Zoom and will provide viewers the opportunity to hear from, and engage with, a range of ASX-listed leading micro/mid cap companies.

To access further details of the event and to register at no cost, please copy and paste the following link into your internet browser:

https://us02web.zoom.us/webinar/register/5416151767246/WN_PZu7bDw3T6elbu04A5cUwA

A recorded copy of the webinar will be made available following the event.

A copy of the investor presentation to be delivered during the webinar is attached.

ENDS

Actinogen Medical

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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 an innovative treatment for cognitive impairment associated with neurological diseases amenable to modifications of raised cortisol levels inside brain cells. 'Cognition' relates to how a person understands and acts in the world around them. Cognitive functions include memory, reasoning, awareness and decision-making, and to a large extent, influence our personality.

Actinogen Medical's lead drug candidate, **Xanamem®**, has been specifically designed to block the production of cortisol – the stress hormone – in the brain. Chronically elevated cortisol is associated with cognitive decline in **Alzheimer's Disease**, potentially linked to cognitive impairment and anxiety in **Fragile X syndrome**, and cognitive impairment in neuropsychiatric diseases.

Xanamem offers a promising new approach to treat cognitive impairment associated with these neurological diseases.

In the Company's recent XanaHES Phase I trial, Xanamem exhibited a statistically significant improvement in cognition among healthy older volunteers, and recent human target engagement data for the drug in the brain suggests good activity of doses as low as 5mg daily. The Company plans to initiate a range of Phase II studies evaluating Xanamem in the treatment of cognitive impairment associated with Alzheimer's disease, Fragile X syndrome, and other indication(s) with a strong scientific rationale.

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 registered trademark of Actinogen Medical.

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This announcement and attachments may contain certain forward-looking statements that are based on subjective estimates and assumptions and relate to circumstances and events that have not taken place and may not take place. Such forward looking statements involve known and unknown risks, uncertainties, and other factors (such as significant business, economic and competitive uncertainties and contingencies, and regulatory and clinical development risks and uncertainties) which may cause the actual results or the performance of Actinogen Medical to be materially different from the results or performance expressed or implied by such forward looking statements. Past performance is not a reliable indicator of future performance. There can be no assurance that any forward-looking statements will be realised. Actinogen Medical does not make any representation or give any warranty as to the likelihood of achievement or reasonableness of any forward-looking statements.

Actinogen Medical encourages all current investors to go paperless by registering their details with the designated registry service provider, Automic Group.



ShareCafe Presentation

Dr. Steven Gourlay: CEO & Managing Director

6 August 2021

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Actinogen snapshot

Actinogen Medical (ASX:ACW) is a public company developing Xanamem[®]; a novel small molecule for cognitive impairment



Favourable drug



Substantial Clinical Data



Attractive targets



Protected & Funded

- ✓ **Brain penetrant**, 11 β -HSD1 enzyme (**cortisol**) inhibitor
- ✓ **Favourable pharmaceutical properties**
- ✓ **Safe** and well tolerated

- ✓ **>200 subjects** treated
- ✓ Significant preclinical and clinical **data generated**
- ✓ **Sub-analysis** completed

- ✓ **Significant opportunity** in Mild Cognitive Impairment due to Alzheimer's disease
- ✓ **Strategic benefits** from Fragile X syndrome¹

- ✓ **Comprehensive patents** in place²
- ✓ **Strong cash balance** with ~\$13.46M in cash as at 30 June 2021

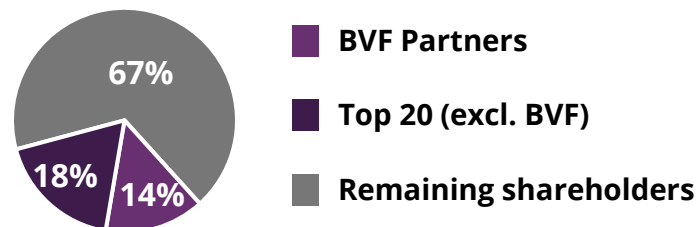
Actinogen is well placed to fully fund its Phase 2 clinical trials and expand the clinical pipeline

Corporate overview

Major shareholders remain supportive through share price appreciation

Major Shareholders

BVF Partners	14.4%
Steven Gourlay ¹	3.8%
Edinburgh Technology Fund	2.9%



Financial Information

52 week high	A\$0.195
52 week low	A\$0.019
Share price (28 July 2021)	A\$0.110
Number of shares	1,660.6M
Market capitalisation (28 July 2021)	A\$182.7M
Net cash ²	A\$13.46M

Experienced Board & Senior Management



Dr. Geoff Brooke
Chairman
MBBS; MBA



Dr. George Morstyn
Non-Executive Director
MBBS; PhD; FRACP; MAICD



Mr. Malcolm McComas
Non-Executive Director
BEC, LLB; FAICD; SF Fin



Dr. Steven Gourlay
CEO & MD
MBBS; FRACP; PhD; MBA

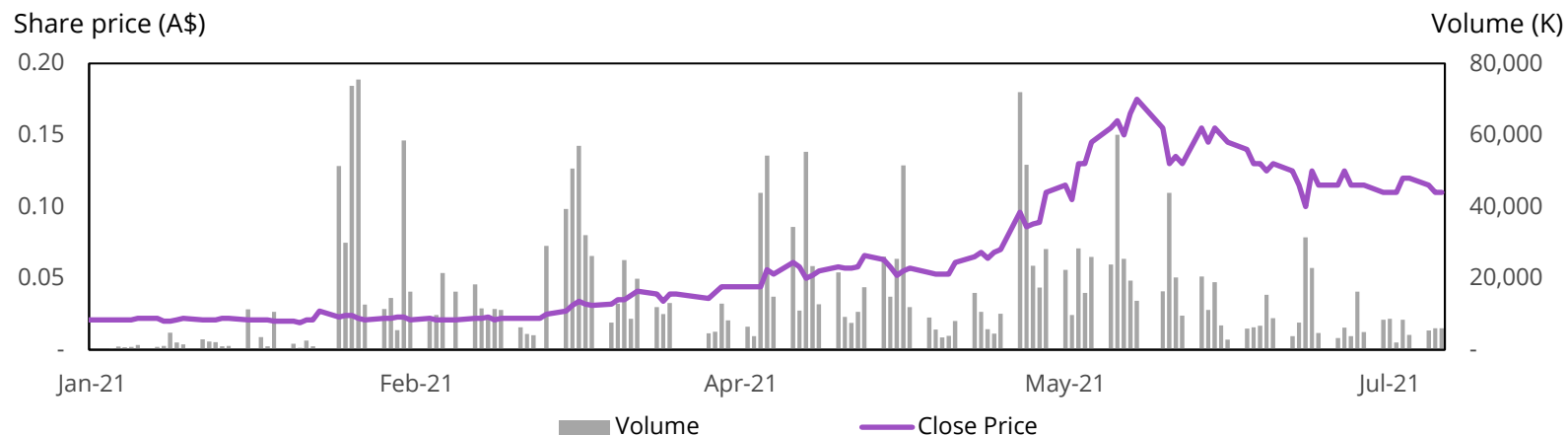


Jeff Carter
Chief Financial Officer
B. Fin Admin; M. App. Fin; CA



Tamara Miller
Vice President Drug Development & Strategy
M.Med; M.PharmSci; BSc; MSc; PMP; CPPM

Share Price Performance³



Source: IRESS

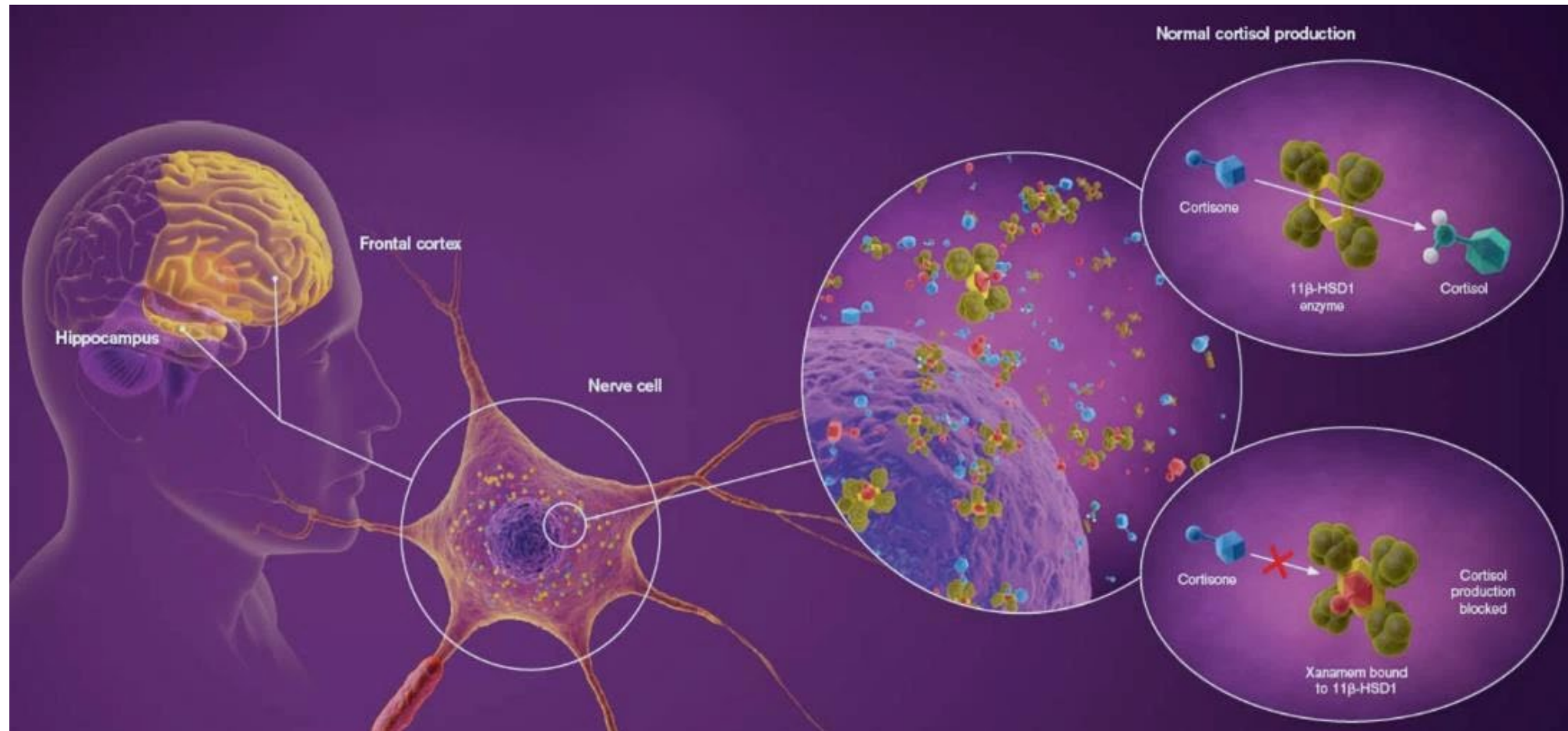
1. Holding based on loan plan shares (~48M), and shares acquired in the 2021 shortfall placement (~15M)

2. Cash as at 30 June 2021

3. Volume traded on 5 Feb 2021 of 283.1M has been capped due to differences in volume.




Xanamem - small molecule drug with a novel mechanism of action

Xanamem is a brain¹ penetrant 11 β -HSD1 small molecule enzyme inhibitor; designed to inhibit excessive cortisol production in the brain



Clinical pipeline for Xanamem

Major clinical trials targeting brain penetration, improved cognition and other benefits

Planned studies	Pathway (illustrative)	Outlook
 <p>Mild cognitive impairment due to Alzheimer's disease</p>	<p>XanaMIA - Commenced Part A: 10mg, 5mg, Placebo Part B: MCI due to AD, biomarkers</p>	<p><i>Potential to address all stages of the disease</i></p>
 <p>Anxiety, sleep & behavioural problems in Fragile X syndrome</p>	<p>FDA Pre-IND Meeting</p> <p>XanaFX - Commence 2H CY21 Phase II trial</p>	<p><i>Positive outcomes expected to lead to a pivotal Phase III trial</i></p>
 <p>Additional indication</p>	<p>Review and finalise selection of additional indication</p> <p>Indication associated with cognitive impairment Phase II trial</p>	<p><i>High unmet need focus with strong scientific rationale</i></p>

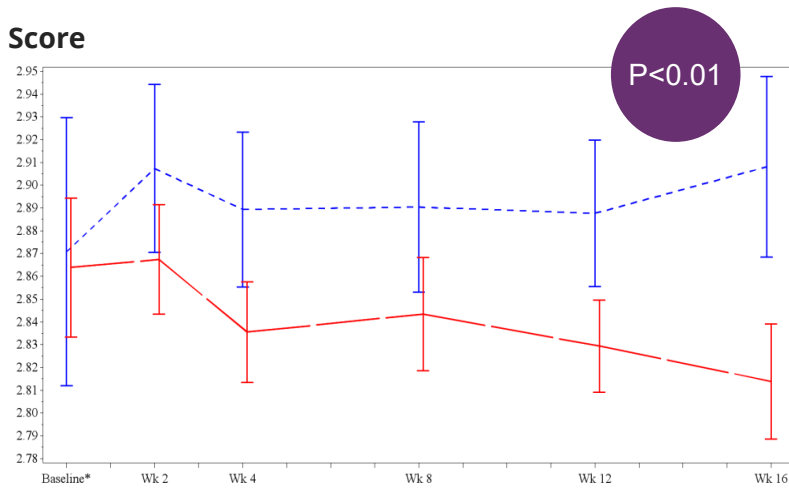


Breakthrough results achieved in Phase 1 study

Phase 1 XanaHES study demonstrated statistically significant cognitive efficacy signal in multiple cognition domains based on Cogstate Cognitive Test Battery as early as 2 weeks¹

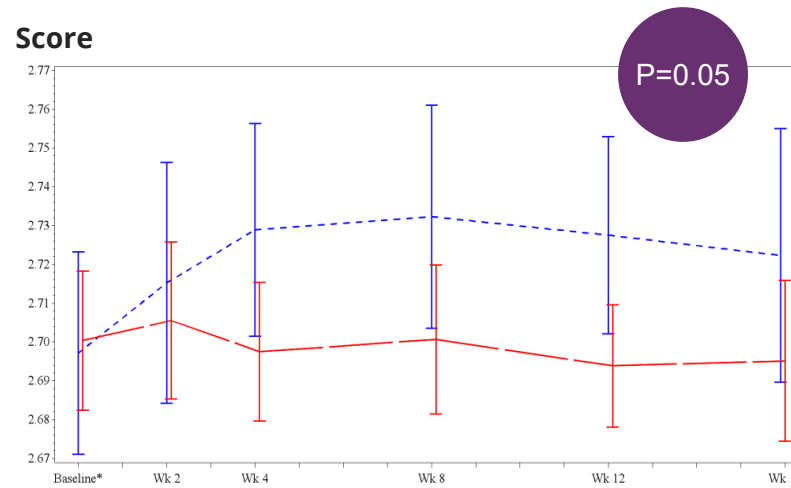
Working memory (One Back Test)

Strongly statistically significant result



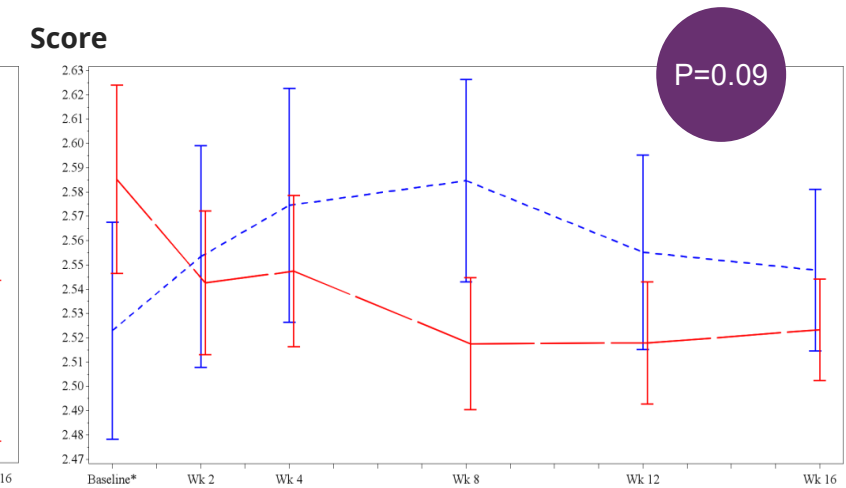
Visual attention (Identification Test)

Statistically significant result



Psychomotor function (Detection Test)

Good trend to a positive result



Treatment Group
 — Xanamem 30pts — Placebo 12 pts

Efficacy results achieved through sensitive and modern testing method which can now be utilised in future studies supported by increasing clinical adoption

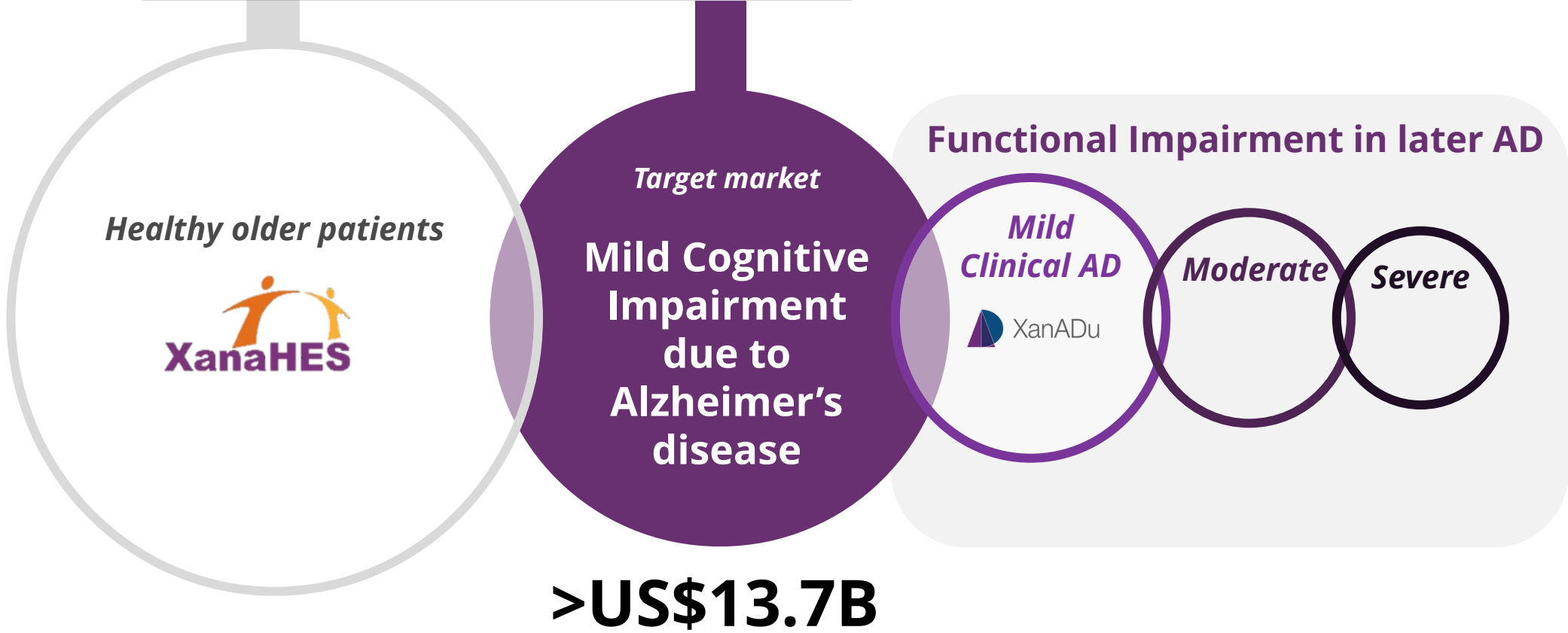
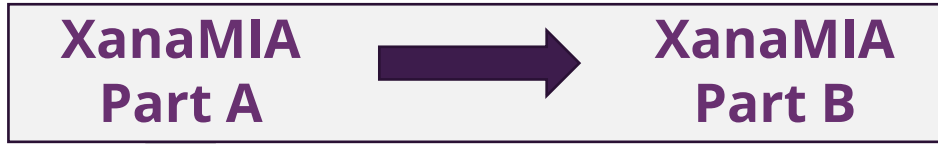


Notes: All values are the means of observed data. p values were calculated with an ANCOVA (analysis of covariance) model using Baseline values as a covariate.
1. XanaHES Phase 1 clinical trial treated healthy elderly patients with 20mg Xanamem daily (n=30 active, n=12 placebo)



Bridging the positive Phase 1 cognition data to Alzheimer's patients

Targeting the first stage of Alzheimer's disease, measuring biomarkers



Target annual peak sales¹



XanaMIA Phase II trial has commenced

XanaMIA trial design is optimised for success

XanaMIA - Part A

(expected results in 1H CY22)

- **Healthy older subjects** - with normal cognition, ≥50 years of age (same as XanaHES trial)
- **Endpoints and testing criteria** - to leverage modern and highly sensitive cognition tests (Cogstate, iDSST)
- **Dose ranging** - at 5mg, 10mg Xanamem once daily

Dose ranging study to healthy elderly to **confirm minimum effective dose of Xanamem**

XanaMIA - Part B

(expected results in CY23)

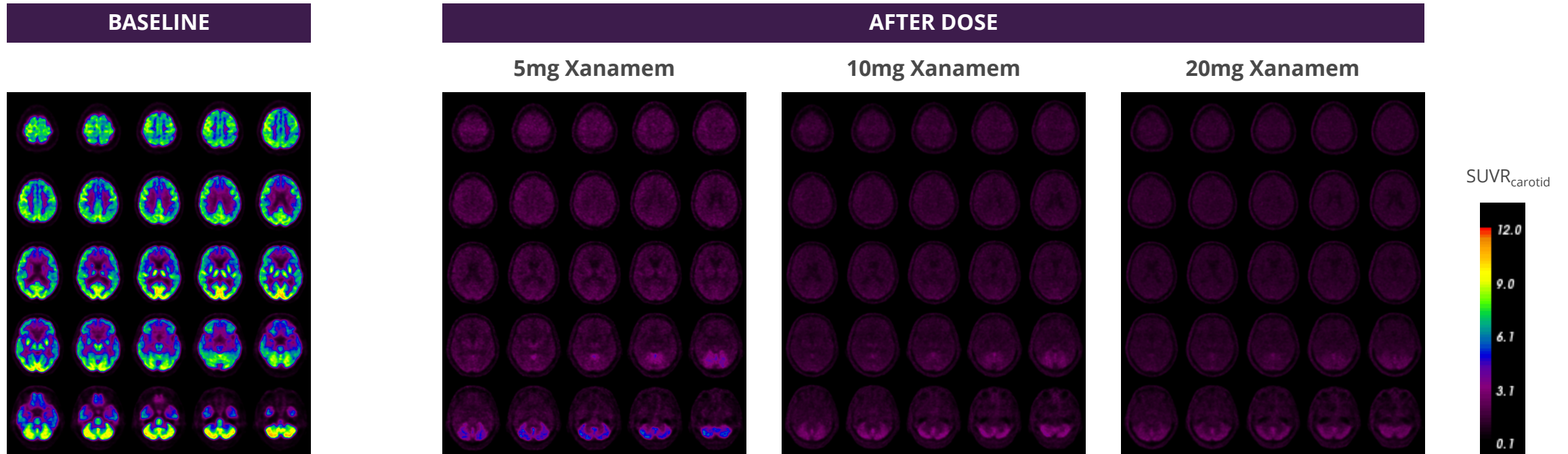
- Targeting subjects with **mild cognitive impairment** due to Alzheimer's disease (using positive serum biomarkers)
- Bridging to patients with **modern and sensitive cognition tests** (Cogstate, iDSST) from Part A plus **biomarkers**
- Introducing other cognitive and functional endpoints that have been **accepted by regulators for later studies**

Phase II trial to **assess efficacy of Xanamem** in patients with MCI due to AD



Review of data supports a low Xanamem dose

Human Target Occupancy Study PET data demonstrates consistent suppression of enzyme activity at 5mg Xanamem doses and above



PET data demonstrates that Xanamem extensively binds to the 11 β -HSD1 enzyme throughout the brain, with high post-treatment effects (absence of colour) after 7 days at all doses, including a 5mg Xanamem dose.

This is consistent with full hormonal pharmacodynamic activity seen with 10mg Xanamem in clinical trials.

XanaMIA Part A is seeking to confirm the minimum effective dose of Xanamem to use going forward.

Fragile X Phase II trial to commence in 2H CY21

Anxiety, sleep and behavioural problems in Fragile X syndrome are often associated with raised cortisol; Xanamem has the potential to improve symptoms



Unmet Medical Need

- Rare genetic condition, with life-long treatment required for patients (management is often complex)
- **There are no approved drugs to treat FXS**



Strategic Benefits

- **Fast-to-market** strategy
- Xanamem in FXS has been awarded **Rare Paediatric Disease Designation**



Data Generation

- **Positive Pre-IND FDA feedback** received for Actinogen's FXS program
- **Presents a significant potential upside with FXS-related conditions**, such as Autism Spectrum Disorder



Valuable Market Opportunity¹

- Estimated **global market size of ~US\$250M**
- FXS occurs in approx. 1 in 2500-4000 males and 1 in 7000-8000 females (averages to 1 / 4500)

Significant value upside for Actinogen



Accelerate clinical development

Expand pipeline to show efficacy

- Expand pipeline with additional indications and clinical trials, providing multiple shots on goal

Enlarge clinical safety dataset

- Generate data to optimise potential partnership discussions

Optimise manufacturing

- Scale up and optimise manufacturing to prepare for commercially viable, large scale production



Potential commercial value

Big Pharma Partnership(s)

- Actively engaging with potential future partners
- High degree of interest worldwide in new Alzheimer's mechanisms

Tradeable PRV voucher

- Eligible through RPDD recently granted by FDA²
- Recently traded for US\$100M-US\$125M³

High Valuations in Alzheimer's Research

- Companies with a lead asset in phase II or III development for AD have valuations of at least US\$350M⁴

1. US\$1B based on the average disclosed values of 13 major global pharmaceutical deals (Oct 2018 to Mar 2020) considered to have material interest in AD (Source: Bio-Link analysis)

2. Eligible for a transferable (including by sale) Priority Review Voucher under Rare Paediatric Disease Designation from the FDA (if Xanamen is first registered in the US for FXS)

3. Potential to receive a Priority Review Voucher (PRV) upon approval in FXS – (Source: PRV value adapted from FDA website; Company press releases; priorityreviewvoucher.org)

4. Vivoryon Therapeutics, phase IIb AD lead asset (EURONEXT Amsterdam: 350 euro / ~US\$500m); Athira Pharma, phase II AD lead asset (NASDAQ GS:US\$370m); Cortexyme, phase III AD lead asset (NASDAQ GS:US\$1.6B) and same drug in phase II for periodontal disease and Parkinson's disease; Cassava Sciences, AD lead asset phase III-ready (NASDAQ GS:US\$2.7B). All companies' value primarily attributed to their lead AD asset. Market capitalisations as of approximately 02Aug2021.

Esteemed Advisory Boards

World-leading, premier academics involved in the development of Xanamem

Xanamem Clinical Advisory Board

Positions Xanamem at the forefront of drug development



Prof. Craig Ritchie
Chair



THE UNIVERSITY
of EDINBURGH



Prof. Colin Masters AO



Prof. Jeffrey Cummings



**Cleveland
Clinic**



Prof. Alan Boyd



Prof. Jonathan Seckl



THE UNIVERSITY
of EDINBURGH



Prof. Brian Walker



**Newcastle
University**



Prof. Scott Webster



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of EDINBURGH

Next steps and key catalysts

Actinogen has a strong balance sheet to execute its strategy and progress Xanamem clinical development

❑ Clinical trials to commence in 2021*

- XanaMIA Part A data expected in 1H2022
- XanaFX data expected 2023
- XanaMIA Part B data expected 2023

❑ Pursue other high priority indications

- Leverage strong academic, grant collaborations
- Start 3rd indication late 2021/early 2022

❑ Expand team to pursue aggressive timelines

❑ Key publications and scientific presentations

