



ASX ANNOUNCEMENT

Actinogen CEO presentation to Spark Plus Healthcare Day

Sydney, 03 November 2022. Actinogen Medical ASX: ACW (“ACW” or “the Company”) is pleased to announce its participation in the Spark Plus *Healthcare Day* webinar to be held **today** from 4:00pm AEDT / 1:00pm AWST / Singapore / Hong Kong.

The webinar can be viewed live via Zoom and will provide investors with the opportunity to hear from and engage with Actinogen’s CEO and Managing Director Dr Steven Gourlay.

Dr Gourlay will provide an overview of Actinogen and focus on the Company’s recent positive Alzheimer’s Disease (AD) Phase 2a trial results that showed a strong clinical effect from its lead compound Xanamem® and a major validation of the ‘cortisol hypothesis’ for AD.

To register for the free webinar, please click on the following link or copy and paste the address into your internet browser:

https://us02web.zoom.us/webinar/register/3016662416846/WN_hg_zoqpnRRuems_eUjfr_A

A copy of Dr Gourlay’s presentation slides is attached.

ENDS

Investors

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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 a novel therapy for neurological and neuropsychiatric diseases associated with dysregulated brain cortisol. There is a strong association between cortisol and detrimental changes in the brain, affecting cognitive function, harm to brain cells and long-term cognitive health.

© Xanamem is a registered trademark of Actinogen Medical Limited

Cognitive function means how a person understands, remembers and thinks clearly. Cognitive functions include memory, attention, reasoning, awareness and decision-making.

Actinogen is currently developing its lead compound, Xanamem,[®] as a promising new therapy for Alzheimer's Disease and Depression and hopes to study Fragile X Syndrome and other neurological and psychiatric diseases in the future. Reducing cortisol inside brain cells could have a positive impact in these and many other diseases. The cognitive dysfunction, behavioural abnormalities, and neuropsychological burden associated with these conditions is debilitating for patients, and there is a substantial unmet medical need for new and improved treatments.

About Xanamem

Xanamem's novel mechanism of action is to block the production of cortisol inside cells through the inhibition of the 11 β -HSD1 enzyme in the brain. Xanamem is designed to get into the brain after it is absorbed in the intestines upon swallowing its capsule.

Chronically elevated cortisol is associated with cognitive decline in Alzheimer's Disease, and Xanamem has shown the ability to enhance cognition in healthy, older volunteers. Cognitive impairment is also a feature in Depression and many other diseases. Cortisol itself is also associated with depressive symptoms and when targeted via other mechanisms has shown some promise in prior clinical trials.

The Company has studied 11 β -HSD1 inhibition by Xanamem in more than 300 volunteers and patients, so far finding a statistically significant improvement in working memory and attention, compared with placebo, in healthy, older volunteers in two consecutive trials and clinically significant improvements in patients with biomarker-positive mild AD. Previously, high levels of target engagement in the brain with doses as low as 5 mg daily have been demonstrated in a human PET imaging study. A series of Phase 2 studies in multiple diseases is being conducted to further confirm and characterize Xanamem's therapeutic potential.

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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This announcement and attachments may contain certain "forward-looking statements" that are not historical facts; are based on subjective estimates, assumptions and qualifications; and relate to circumstances and events that have not taken place and may not take place. Such forward looking statements should be considered "at-risk statements" - not to be relied upon as they are subject to known and unknown risks, uncertainties and other factors (such as significant business, economic and competitive uncertainties / contingencies and regulatory and clinical development risks, future outcomes and uncertainties) that may lead to actual results being materially different from any forward looking statement or the performance expressed or implied by such forward looking statements. You are cautioned not to place undue reliance on these forward-looking statements that speak only as of the date hereof. Actinogen Medical does not undertake any obligation to revise such statements to reflect events or any change in circumstances arising after the date hereof, or to reflect the occurrence of or non-occurrence of any future events. Past performance is not a reliable indicator of future performance. Actinogen Medical does not make any guarantee, representation or warranty as to the likelihood of achievement or reasonableness of any forward-looking statements and there can be no assurance or guarantee that any forward-looking statements will be realised.

ACTINOGEN MEDICAL ENCOURAGES ALL CURRENT INVESTORS TO GO PAPERLESS BY REGISTERING THEIR DETAILS WITH THE DESIGNATED REGISTRY SERVICE PROVIDER, AUTOMIC GROUP.

[®] Xanamem is a registered trademark of Actinogen Medical Limited



Alzheimer's Disease biomarker study validates Xanamem[®] program

Positive Phase 2a clinical data with large CDR-SB effect size

Dr. Steven Gourlay MBBS PhD MBA, CEO & MD

SparkPlus Healthcare Day, 3 November 2022

Authorised by the Board of Directors of Actinogen Medical Limited

Disclaimer

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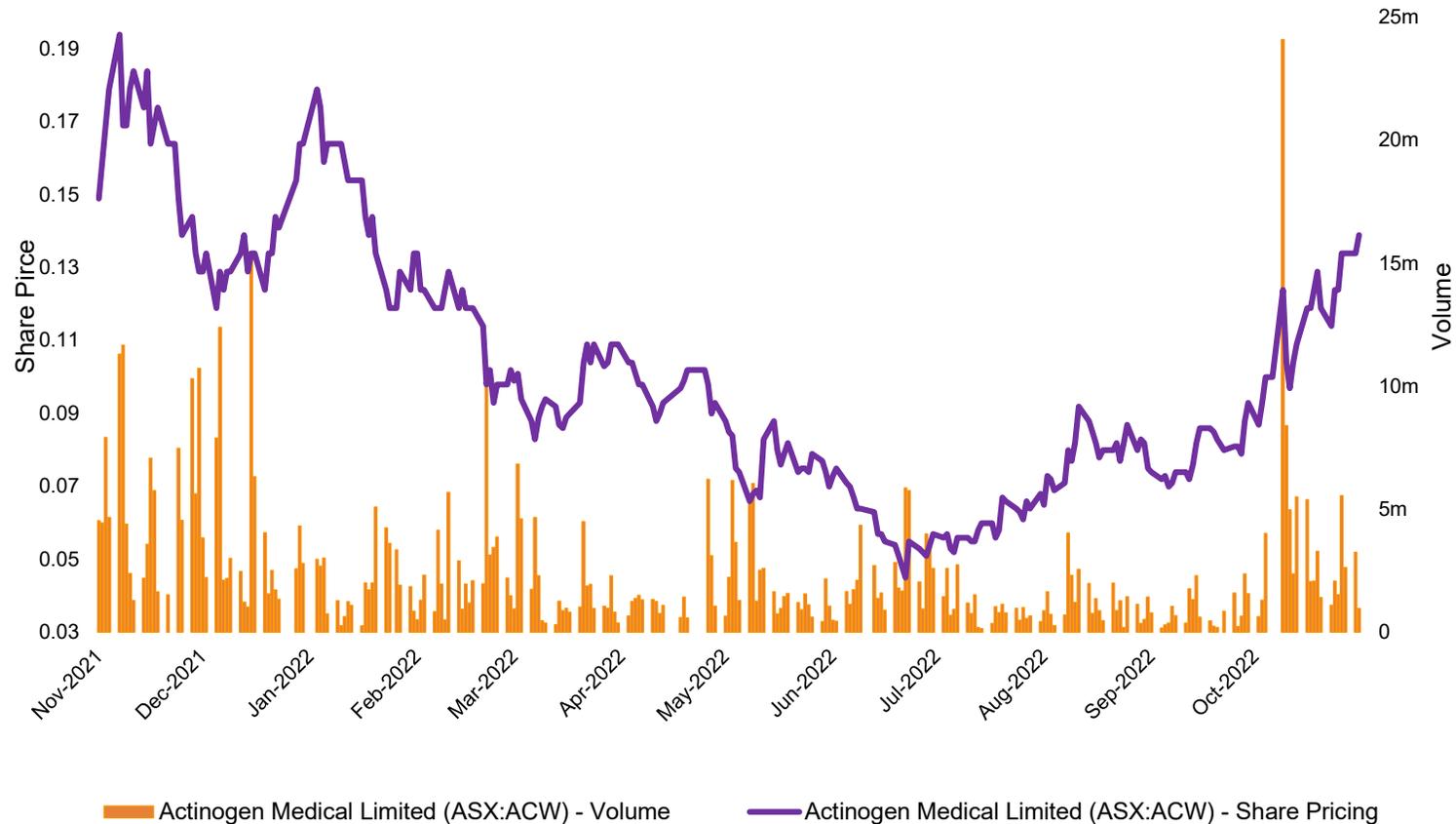
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ACW top stockholders and stock price



Share price chart at 01 November 2022

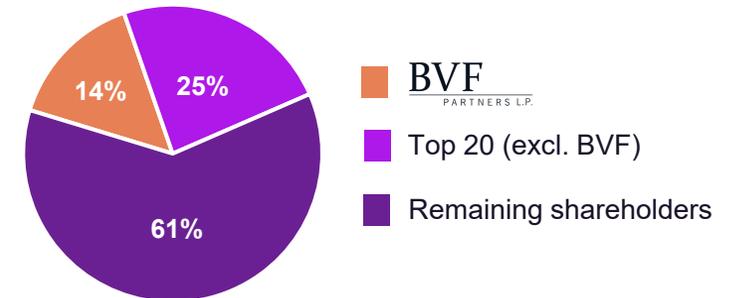


Trading Information

52 week high	A\$0.20
52 week low	A\$0.04
Number of issued shares	1,796M
Market capitalisation (01 Nov 2022)	A\$242M
Cash Balance at 30 Sep 2022	A\$17M ¹

Major Shareholders

BVF Partners	13.9%
Steven Gourlay	3.7%
Edinburgh Technology Fund	2.7%



¹ Including receivable of A\$4 million for R&D tax credit

Leadership and Management



Extensive drug development and commercial experience

Experienced Board of Directors...



Dr. Geoff Brooke

Chairman

MBBS; MBA



- 30+ years experience in the healthcare investment industry
- Founder and MD of Medvest Inc and GBS Ventures, Chairman of Cynata Therapeutics, Board Member of Acrux



Dr. George Morstyn

Non-Executive Director

MBBS; PhD; FRACP; MAICD



- 25+ years experience in biotech investment and drug development
- Board member of Cancer Therapeutics and Symbio



Mr. Malcolm McComas

Non-Executive Director

BEC, LLB; FAICD; SF Fin



- 25+ years experience in the financial services industry
- Chairman of Pharmaxis and Fitzroy River Corporation



Dr. Steven Gourlay

CEO & MD

MBBS; FRACP; PhD; MBA



- 30+ years experience in development of novel therapeutics
- Former founding CMO at US-based Principia Biopharma Inc

See full team and bios at:
<https://actinogen.com.au/our-company/#about-us>

...with a talented management team in place



Jeff Carter

Chief Financial Officer

B. Fin Admin; M. App. Fin; CA



Tamara Miller

SVP Product Development

M.Med Sci; BSc; MSc; PMP; CPPM



Dr Paul Rolan

Chief Medical Officer

MD, FRACP



Cheryl Townsend

VP Clinical Operations

RN, M Health Law



Dr Christian Touli

Head of Business Development

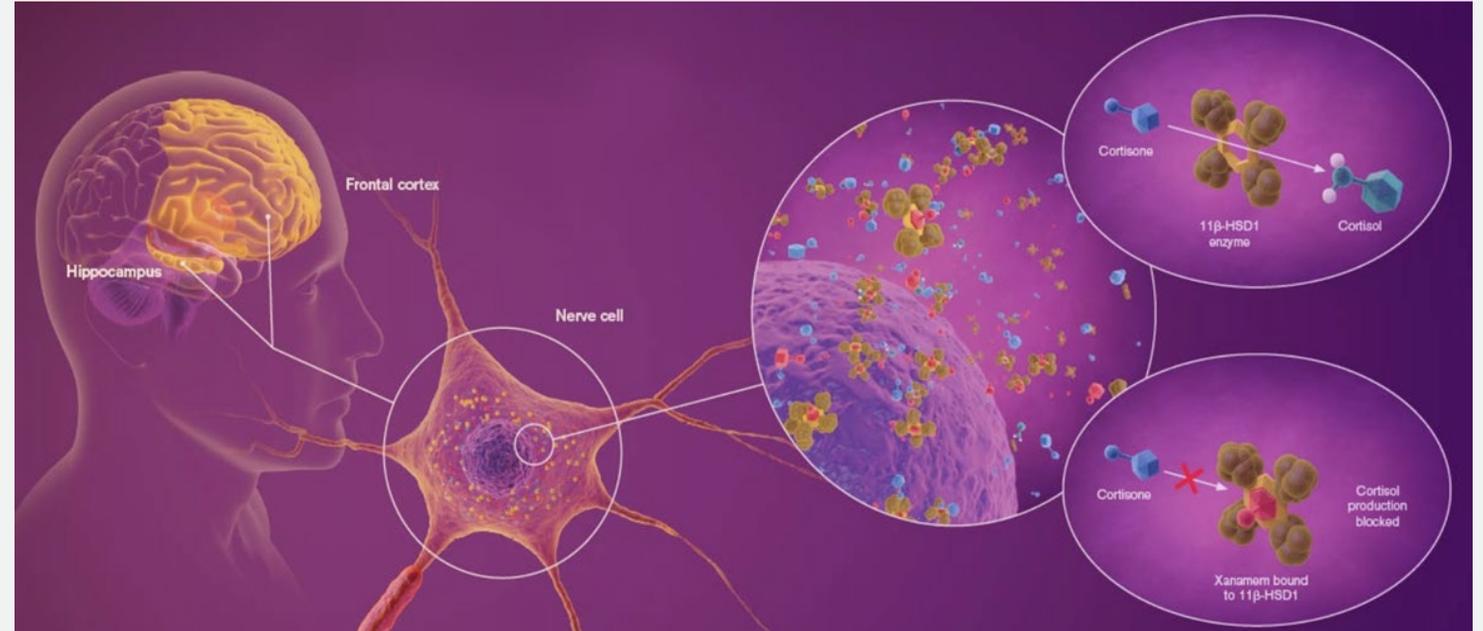
PhD; GAICD

Xanamem: Oral, low dose, once-a-day treatment with a unique non-amyloid mechanism

Brain penetrant 11 β -HSD1 small molecule enzyme inhibitor reduces cortisol inside brain cells - modulating signaling pathways and underlying disease processes^{1,2}

Potential to be:

- Rapidly cognitive enhancing
- Disease-modifying (slow or halt progression) in AD
- Anti-depressant

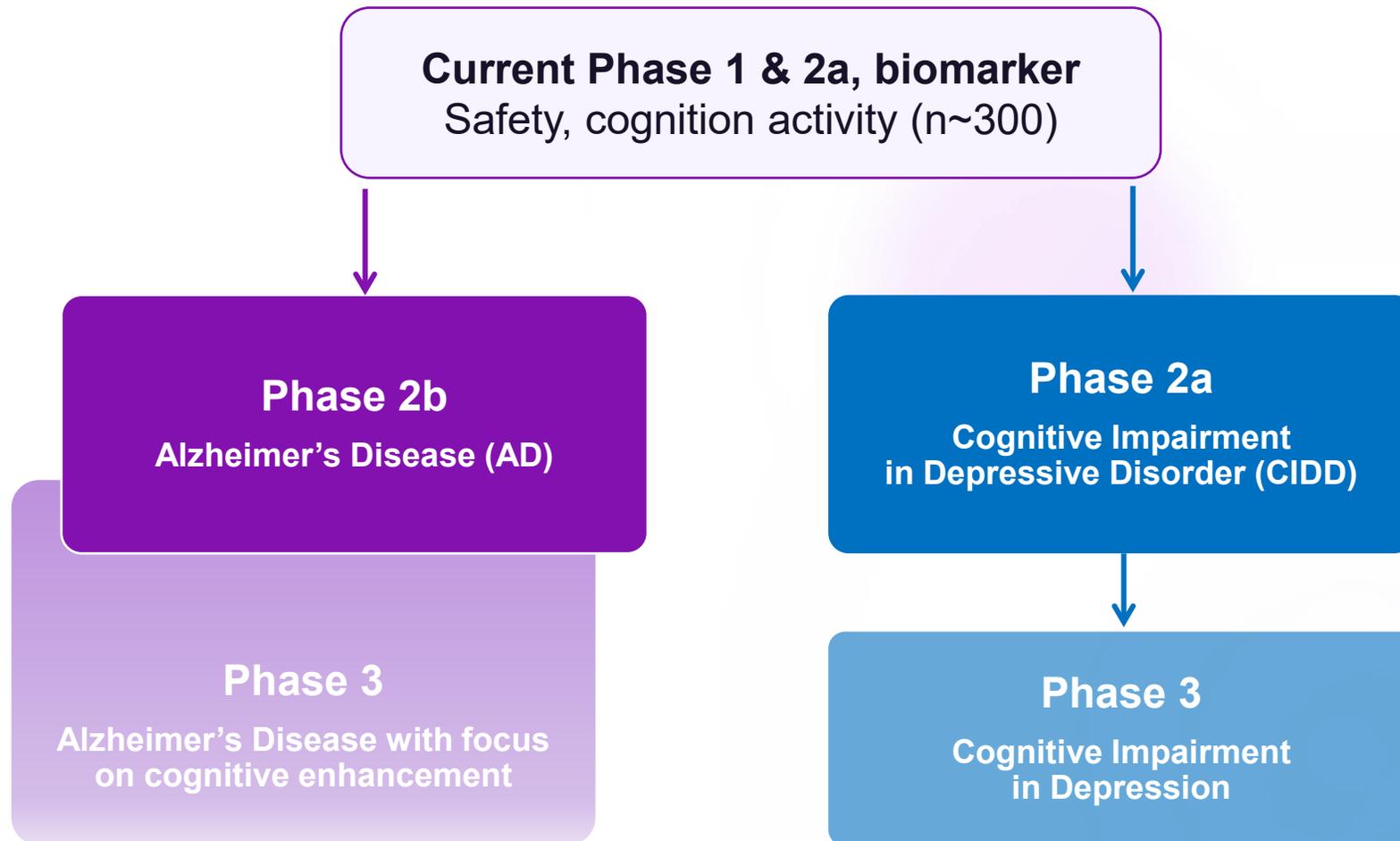


1. Xanamem® is a CNS (Central Nervous System) penetrant small molecule based on human PET scan evidence and cerebrospinal fluid (CSF) measurements
2. Sooy et al. 2015 showing effects on amyloid plaque reduction in an aged mouse model after 28 days associated with increases in insulin degrading enzyme; Popoli et al. 2011 microglial cell modulation in rats, effects on glutamate, cannabinoid and other signalling pathways

Xanamem Phase 2 & 3 program



Building on four independent Phase 1 and 2 studies showing activity



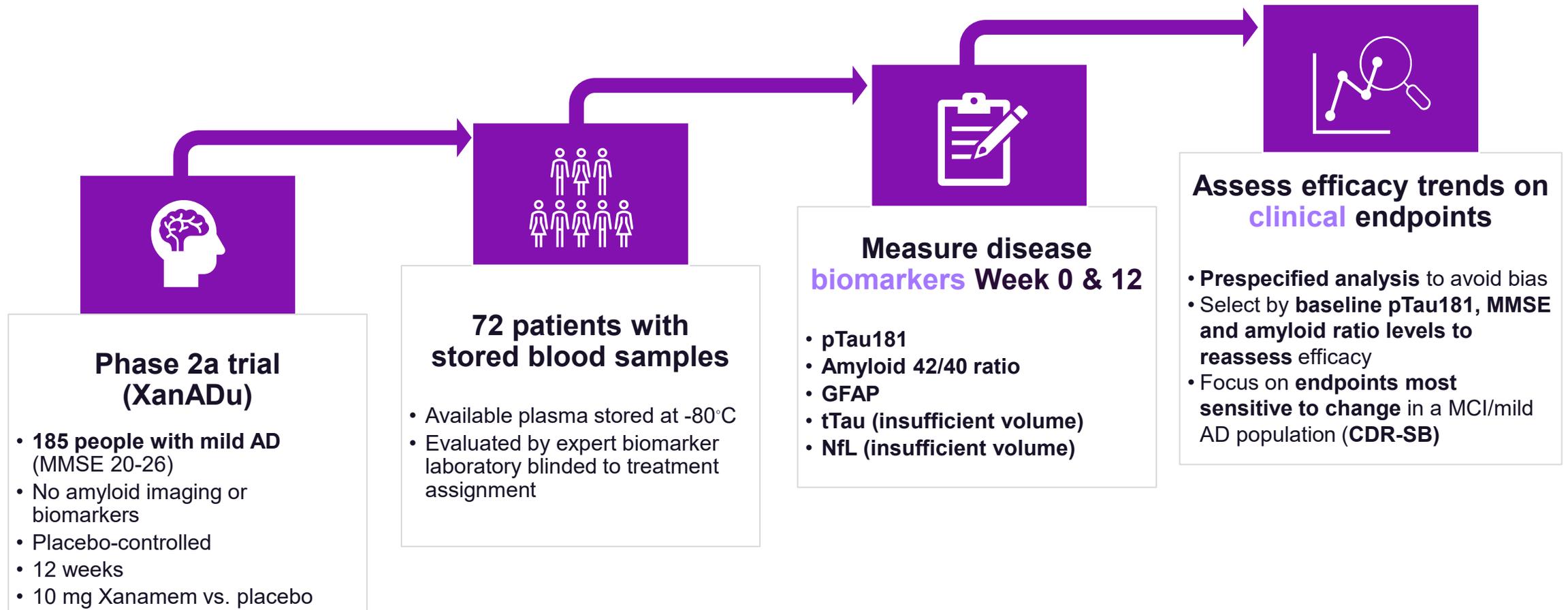
Previously: evidence of Xanamem activity in cognition from multiple sources

- ✓ **In animals**
 - ✓ **Protection against cognitive decline in animal model of AD using a Xanamem analogue independent of amyloid plaque**
- ✓ **In humans**
 - ✓ **PET scan study showing high levels of target binding at doses of 5 mg and above**
 - ✓ **Consistent target engagement measured by ACTH response**
 - ✓ **XanaHES trial in cognitively normal older volunteers – Cogstate attention & working memory**
 - ✓ **XanaMIA trial in cognitively normal older volunteers – Cogstate attention & working memory**

Human and animal data support Xanamem activity at doses of 5 to 10 mg daily

Phase 2 blood biomarker study design & methods

Uses a pre-specified protocol and analysis plan



Creates valuable data relating to patient selection and efficacy in a mild AD population

New Alzheimer's Disease (AD) key clinical findings

Design

- Phase 2a placebo-controlled trial of Xanomem 10 mg vs. placebo over 12 weeks was re-run in 72 patients with mild AD who had biomarker samples available
- Used a pre-specified protocol & analysis plan to avoid bias

Major findings

- CDR-SB effect in patients with elevated blood pTau as a diagnostic for AD
 - ✓ 60-80% relative reduction in progression of disease over 12 weeks
 - ✓ Effect size of 0.6 – 0.8 points is larger than the 0.45 points reported recently for the successful CLARITY trial of lecanemab¹ (amyloid antibody)
 - ✓ Corroborated by positive trends in a Neurologic Test Battery (NTB) of executive function & Mini Mental State Exam (MMSE)

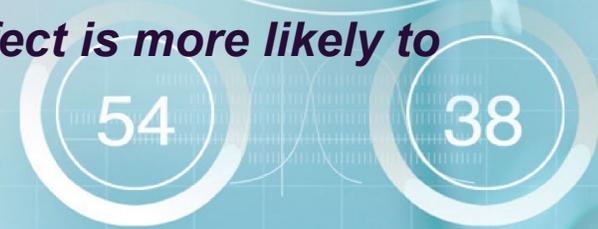
Implications

- Regulatory path to approval clear and uncontroversial with FDA-approved CDR-SB

Eminent world-leading authority on dementia, Associate Professor Michael Woodward, commented:

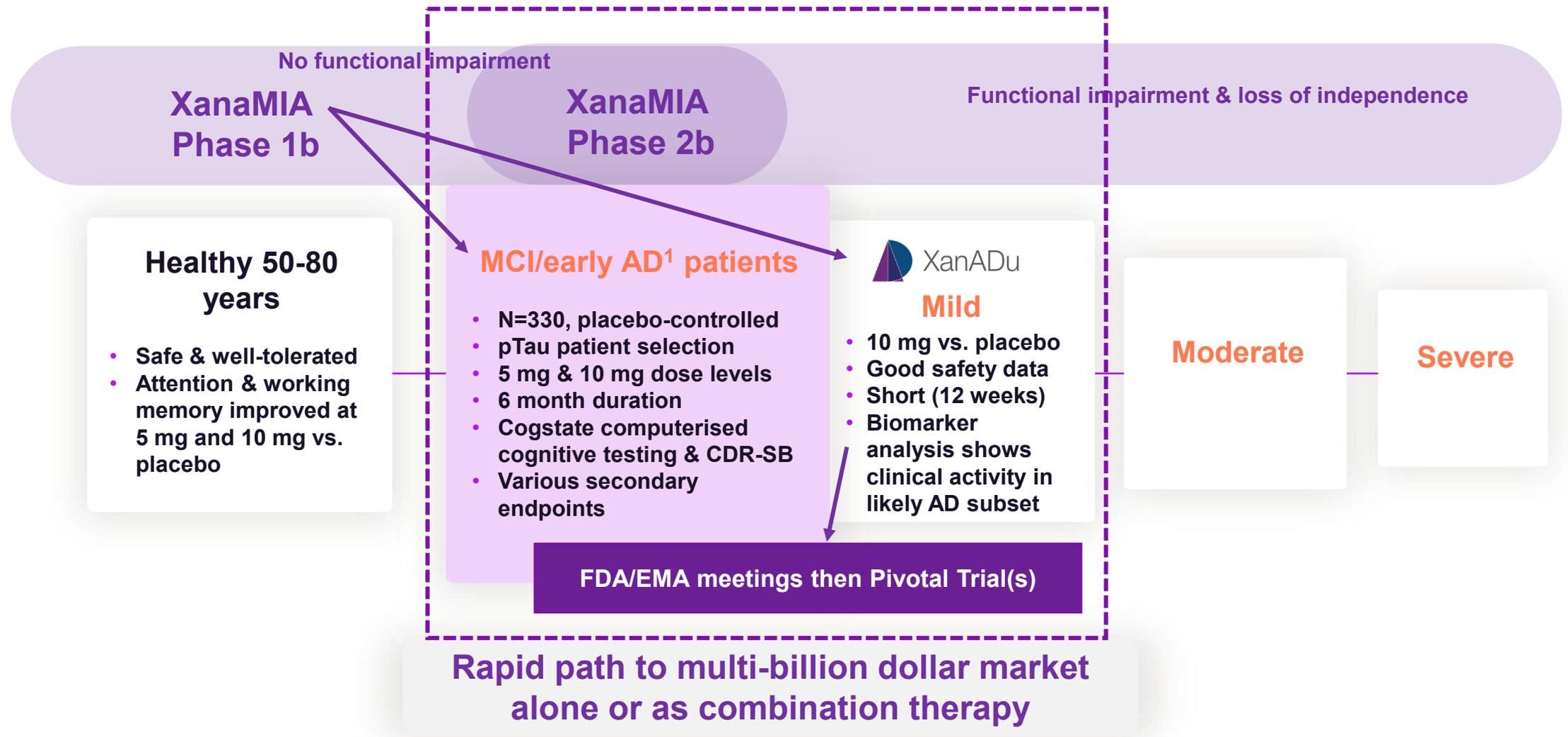
“The positive data for CDR-SB and other endpoints are encouraging and indicate a likely therapeutic effect of Xanomem in patients with the early stages of Alzheimer’s Disease.

The use of pTau blood levels to confirm the diagnosis of Alzheimer’s Disease in future trials represents a practical and efficient method to select patients at risk of disease progression and in whom a treatment effect is more likely to be observed.”





Focus on speed to market as a cognitive enhancing treatment



1. Mild Cognitive Impairment (MCI): memory, executive function deterioration with retained functional abilities; very mild AD with some functional impairment

Actinogen has the only non-amyloid mechanism drug in development with credible cognitive data



It is one of only three worldwide AD clinical trial programs for an oral medication with credible cognitive activity data

Mechanism	Stage	Cognitive endpoint	Company market cap. (\$AU) ¹
Oral Xanamem to lower brain cortisol (Actinogen)	Phase 2	Cognitive test battery, CDR-SB, NTB	230 million
Oral inhibition filamin A to stop A β 42 amyloid signal to TLR/ α 7nicR (Cassava Sciences)	Phase 3	Cognitive test battery	2.3 billion
Oral QPCT inhibitor to prevent toxic amyloid formation (Vivoryon)	Phase 2	Cognitive test battery	280 million

Xanamem is unique with 3 independent trials now showing cognitive and clinical benefits relevant to AD and other diseases

The Xanamem opportunity in depression

Current anti-depressants



work slowly (3 weeks) and
initial suicide risk



do not target cognition



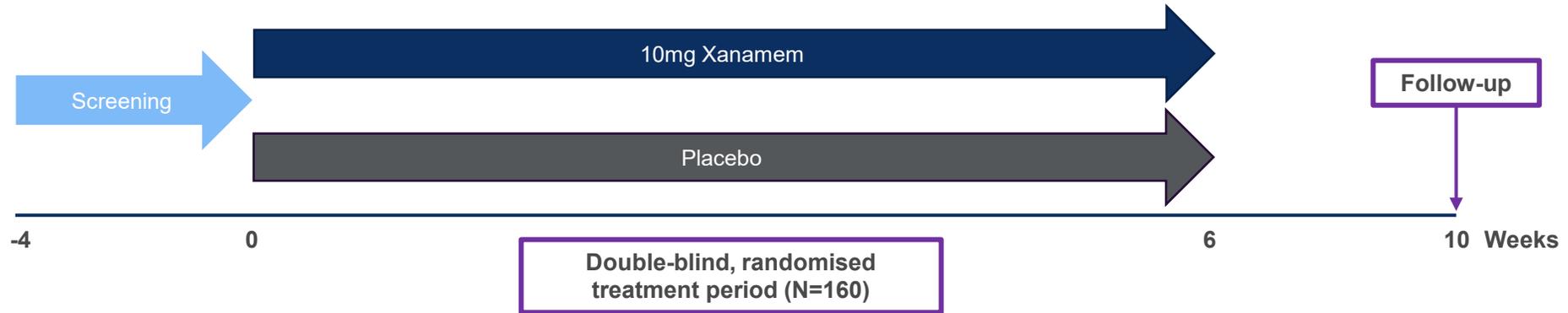
multiple adverse effects
blood pressure, sexual function, appetite...



Xanamem improves cognition quickly

Xanamem may improve both depression and cognitive impairment

XanaCIDD trial design & implementation model



Key inclusion/exclusion criteria	Primary Endpoints	Key Secondary Endpoints	Key Implementation Features
<ul style="list-style-type: none"> Primary diagnosis of MDD Persistent depressive symptoms despite existing therapy Cognitive impairment relative to demographic norms 	<ul style="list-style-type: none"> Cogstate CTB attentional composite (attention and working memory) 	<ul style="list-style-type: none"> Montgomery-Åsberg Depression Rating Scale (MADRS) Executive Function Cognitive Composite Memory Function Cognitive Composite 	<ul style="list-style-type: none"> Australian trial sites Actinogen “hands-on” operational model First patient enrollment planned for 2022

Actinogen strategy validated by new results

Backed by strong balance sheet and intellectual property

Accelerate clinical development

- **Focus on cognitive enhancement:**
 - Patients with early Alzheimer's Disease
 - Use pTau for patient selection
 - Phase 2b will use commercial tablets
 - Cognitive enhancement Depression Phase 2
 - Trial operations based in Australia and selected other countries

Forward planning

- Scale up and optimise **manufacturing** to prepare for commercially viable, large scale production
- **Ancillary clinical and nonclinical** studies
- **Commercial** planning

Create value from partnerships



Pharma/biotech engagement

- **Actively engage large and mid-size potential partners with new results**
 - Seek value-add partnerships
 - Evaluate regional opportunities



Regulatory engagement

- **Seek early US FDA and EMA** interactions to agree endpoints for pivotal, approvable trials in AD



Xanamem timeline & catalysts



2022

- October **multiple partnering presentations of new results**
- November **CTAD XanaMIA presentation**
- Trial **enrollment starts for XanaCIDD** trial in Depression
- Key global **regulatory submissions** in AD with FDA, EMA, other
- Phase 2b XanaMIA **AD trial preparation**

2023

- **Partnering discussions**
- **XanaMIA Phase 2b** enrollment starts H1
- **XanaCIDD** enrollment \pm results
- **Presentations & publications**

2024

- **XanaMIA Phase 2b results**
- **Expand Cognitive/Depression** program
- **Expand Alzheimer's Disease** program

Questions



Thank you

If you have any questions following the webinar please contact:

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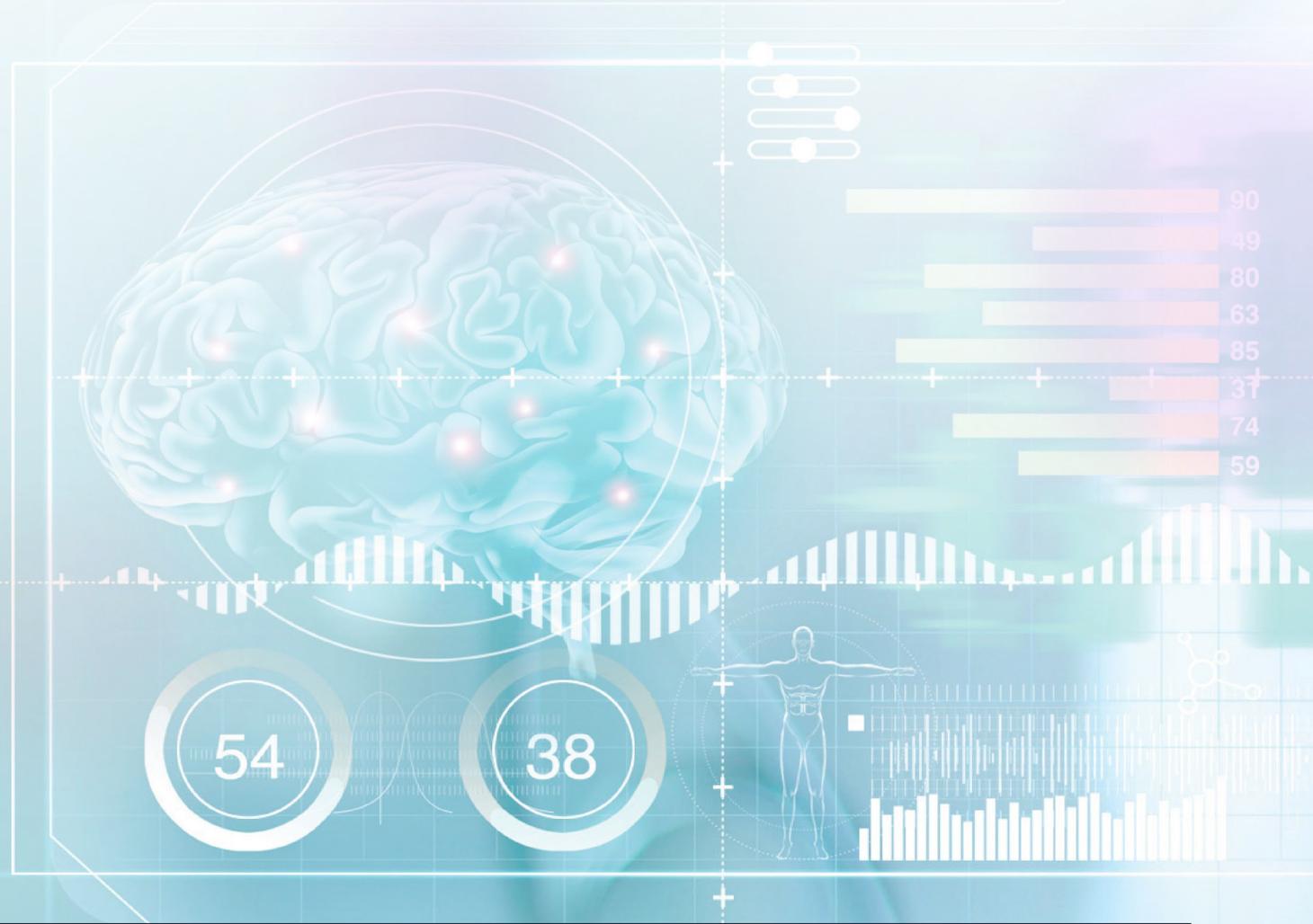
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Appendix



Actinogen company snapshot



Actinogen Medical (ASX:ACW) is developing a novel oral treatment with rapid onset of clinical activity to improve cognition and quality of life



Favourable pharmaceutical properties

- ✓ Demonstrated target engagement in brain and HPA axis¹ in human trials
- ✓ **Low dose, ≤10mg**
- ✓ Low drug-drug interaction potential suitable for combination therapy



Substantial clinical data

- ✓ **>300 subjects or patients safely treated**
- ✓ Cognitive enhancement activity (attention & working memory) - two trials
- ✓ Large **CDR-SB effect** in pTau-positive AD of 0.6-0.8 points - Phase 2a data



Attractive disease indications and rationale

- ✓ **Strong cortisol rationale for treatment of multiple diseases:** early stages of Alzheimer's Disease; Depression & related cognitive impairment; Fragile X Syndrome; and many others



Protected and funded

- ✓ Molecule in-licensed from U Edinburgh in 2014
- ✓ Comprehensive patents in place²
- ✓ **Cash position ~A\$17M incl. receivables at 30 Sep 2022**



High functioning semi-virtual company model

- ✓ Core team of 10 fulltime employees based in Australia
- ✓ Leveraging senior consultants in various fields in Australia, Asia, UK and USA
- ✓ **Australian-based operations gains 43.5% as cash rebate**

1. Hypothalamic-Pituitary-Adrenal axis (body's system to regulate blood levels of cortisol)
2. Composition of matter to 2031 plus 5-year extension in most countries, new patents published and in process

International Cognition Clinical Advisory Board



Global thought leaders in clinical trials for assessment of cognition



Prof. John Harrison

Metis Cognition Ltd

- Expert psychologist with a special interest in cognition
- Chartered psychologist with two PhDs and author/co-author of more than 80 books and scientific articles
- Principal Consultant at Metis Cognition, which advises on selection and integration of cognitive testing into therapeutic development programs



Dr Dana C. Hilt



- 25+ years of drug development experience, primarily of Central Nervous System (CNS) drugs
- Deep experience in Phases 1 to 4 drug development
- CMO at Frequency Therapeutics and has held senior management positions as Chief Medical Officer at various pharmaceutical companies



Dr Christina Kurre Olsen

ORPHA Z YME

- 20+ years research expertise in neuroscience, neuropsychopharmacology, CNS therapeutics and monoclonal antibody immunotherapy
- Strong hands-on knowledge across drug development value chain and a passion for cognition
- Medical Director at Orphazyme A/S



Prof. Paul Maruff



- Chief Innovation Officer at Cogstate Ltd
- Professor in Neuroscience at the Florey Institute of Neuroscience and in Psychology Monash University, Melbourne Australia
- Senior management committee of the Australian Imaging, Biomarkers and Lifestyle (AIBL) study of Alzheimer's Disease
- Involved in the development and approval of 13 new drugs that affect cognition including most recently esketamine for treatment resistant depression



A/Prof Christopher Chen



- Senior Clinician-Scientist, Associate Professor at the Departments of Pharmacology and Psychological Medicine, Yong Loo Lin School of Medicine, National University of Singapore, and Director of the Memory Aging and Cognition Centre, National University Healthcare System.
- Major research and clinical interests are in neuroimaging, molecular biology and treatment of stroke and dementia.
- President of the Asian Society Against Dementia, Secretary-Treasurer of the Asian & Oceanian Association of Neurology.

International Scientific Advisory Boards



Thought-leader academics involved in the development of Xanamem

Alzheimer's Disease Clinical Advisory Board



Prof. Craig Ritchie

Chair



- World-leading authority on dementia; senior investigator on 30+ drug trials
- Chair of the Scottish Dementia Research Consortium; Professor of the Psychiatry of Ageing' Director of the Centre for Dementia Prevention (University of Edinburgh)



Prof. Colin Masters
AO



- 35+ years research on Alzheimer's Disease and other neurodegenerative diseases
- Laureate Professor of Dementia Research and Head, Neurodegeneration Division at The Florey Institute (UniMelb)



Prof. Jeffrey Cummings



- World-renowned Alzheimer's researcher and leader of clinical trials
- MD, ScD; Founding Director of the Cleveland Clinic Lou Ruvo Center for Brain Health
- Recognised for his work through various awards



Prof. Jonathan Seckl



- Undertaken extensive research in endocrinology
- Senior VP at the university of Edinburgh; Chaired Panels for MRC, Innovate UK and Wellcome Trust
- MBBS UCL, PhD (London)



Prof. Brian Walker



- 20+ years research in the area of disease
- Extensive experience advising for pharmaceutical R&D
- Pro Vice Chancellor for Research Strategy & Resources at Newcastle University, UK

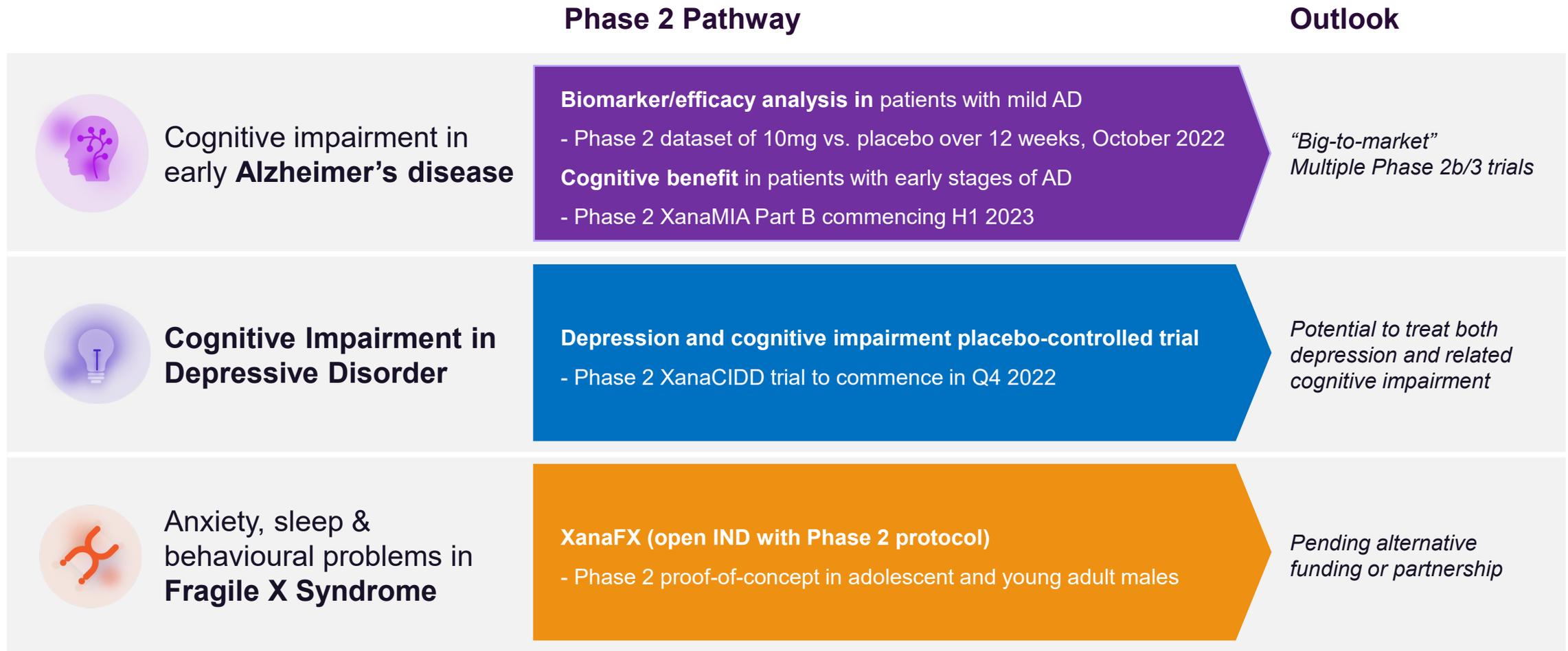


Prof. Scott Webster



- Chair of Medicines at the Centre of Cardiovascular Science, University of Edinburgh
- Former positions across both biotech and academia
- Founder and Chief Scientific Officer at Kynos Therapeutics

Xanamem Clinical Development Pipeline



Selected glossary 1



11 β -HSD1 11 beta HydroxySteroid Dehydrogenase-1 enzyme

A β Amyloid beta – a type of amyloid protein associated with Alzheimer’s Disease, 42 and 40 are different forms

ACTH Adrenocorticotrophic hormone that regulates blood levels of cortisol

ADAS-Cog Alzheimer’s Disease Assessment Score - Cognition

ApoE4 Apoprotein genotype associated with genetic risk of Alzheimer’s Disease

ATN Amyloid, Tau, Neurodegeneration

Clinical scales Measure how a patient feels, performs and functions

CDR-SB Clinical Dementia Rating “Sum of Boxes” scale measuring cognition and function on an 18-point scale (high worse)

CNS Central nervous system

CSF Cerebrospinal fluid

CTAD Clinical Trials on Alzheimer’s Disease (conference)

CTB Cognitive Test Battery of computerized tests

Double-blind Investigators, participants and company do not know who has active vs placebo treatment during a trial

EMA European Medicines Agency

FDA US Food & Drug Administration

GFAP Glial Fibrillary Acidic Protein – a marker of microglial cell activation in the brain

Filamen A Filament protein believed to relate to amyloid toxicity

IDSST International Digit Symbol Substitution Test of cognition

Selected glossary 2



IQCODE Informant Questionnaire on Cognitive Decline in the Elderly

MCI Mild Cognitive Impairment – memory, executive function deterioration with retained functional abilities

MDD Major Depressive Disorder

MMSE Mini Mental State Examination – a 30-point scale of simple questions to assess mental abilities

NfL Neurofilament Light – a nerve protein in the brain and rest of the body too

NIA-AA National Institutes of Aging and Alzheimer's Association

NMDA a type of receptor for glutamate in the brain

NPI Neuropsychiatric Inventory to assess psychiatric symptoms

NTB a Neurologic Test Battery, in this presentation one designed to measure executive function aspects of cognition

PET Positron Emission Tomography – a type of body scan

Placebo controlled Non-active treatment for double-blind design

p-Tau181 or 217 AD biomarker of phosphorylated Tau protein

QPCT Glutaminy-peptide cyclotransferase is an enzyme proposed to create toxic amyloid species

RAVLT Rey Auditory Visual Learning Test

RBANS Repeatable Battery for the Assessment of Neuropsychological Status (a test of mental abilities)

ROC AUC Receiver Operating Curve Area Under the Curve (1.0 ideal) – a type of statistical test to compared two methods of measurement

Tau – a brain protein

Ttau – total tau levels including both phosphorylated and non-phosphorylated tau