

ASX ANNOUNCEMENT**Strategic Update and Teleconference Call Notification**

Sydney, 21 April 2021. Actinogen Medical ASX: ACW ('ACW' or 'the Company') is pleased to provide a strategic update and release a corporate investor presentation. Actinogen's Chief Executive Officer and Managing Director, Dr Steven Gourlay, will be hosting a teleconference on Friday, 23 April 2021 at 9.00am AEST. This teleconference will be used to update existing shareholders, potential investors and other strategic parties on Actinogen's clinical development pipeline, commercial strategy and outlook going forward.

Key highlights:

- **Xanamem™ is a brain penetrant 11β-HSD1 small molecule enzyme inhibitor, that works to inhibit excess cortisol production inside brain cells**
- **Review of data completed to optimise clinical trial planning, with Phase I data highlighting modern and sensitive, computerised measurement tools and PET brain scan data supporting efficacy of Xanamem in doses as low as 5mg**
- **XanaMIA Phase II trial to commence in CY21 and to be executed in two parts;**
 - Part A: Dose ranging study seeking to confirm minimum effective Xanamem dose
 - Part B: Investigating efficacy of Xanamem in patients with mild cognitive impairment due to Alzheimer's disease, bridging positive Phase I data (healthy older subjects and PET brain scan data) to an early stage Alzheimer's population
- **XanaFX Phase II trial in adolescents with Fragile X syndrome is fully funded, with strategic benefits from Rare Paediatric Disease Designation awarded by the FDA supporting clinical development and a pre-IND interaction with the FDA pending**
- **Strong cash balance of ~\$15.23m as 31 March 2021, with XanaMIA and XanaFX fully funded**
- **Dr Steven Gourlay to deliver presentation on a Teleconference at 9:00am on Friday, 23 April 2021**

Dr Steven Gourlay, Actinogen CEO and MD, commented:

"After many years of working in the biopharma industry, I am excited by the huge potential of Actinogen. In my last major role at Principia Biopharma as Chief Medical Officer, I steered two small molecules from a microcap company valuation, through successful Phase II development and into Phase III, resulting in a significant value appreciation for shareholders when the company was acquired for US\$3.7B. I find Actinogen to be a similar investment opportunity: excellent science, a promising Phase II molecule for multiple indications, with an attractive valuation, and so accepted the role as CEO / MD, and personally invested over A\$300K into the Company prior to my appointment.

We are now planning for multiple shots on goal and strongly believe the upcoming trials are designed to achieve informative and positive outcomes. I look forward to working with the team to further develop Xanamem as we progress the development pipeline."

Alzheimer's disease remains a focus for Actinogen, with the XanaMIA trial expected to commence this year. This trial is designed to leverage the positive Phase I cognition data in healthy elderly subjects to bridge the gap to an early Alzheimer's population, with the potential to limit further impairments as Alzheimer's progresses. XanaMIA is planned to utilise the sensitive Cogstate Neurological Test Battery ("Cogstate"), a

computerised test battery measuring a range of cognitive capabilities which was used in the Phase I trial, including the Digit Symbol Substitution Test or iDSST. The iDSST has been recognised in the past by the FDA as an approvable endpoint for a cognitive marketing claim. The PET human brain scan data generated in Actinogen's Target Occupancy study supports daily doses as low as 5mg.

XanaMIA Part A is a dose ranging study designed to confirm the minimum effective dose of Xanamem before moving into larger trials. The study will assess healthy elderly patients at 5mg, 10mg and placebo. The results will be used to inform XanaMIA Part B, which will investigate the efficacy of Xanamem in patients with mild cognitive impairment (MCI) due to Alzheimer's disease. The trial has been designed to utilise serum biomarkers to positively identify MCI as related to Alzheimer's, and dementia assessment scales to ensure patients are early stage, and do not have the functional impairment present in later stage Alzheimer's. Part B endpoints will also include Cogstate and iDSST, as well as other endpoints previously accepted by regulators.

Plans for the XanaFX Phase II trial targeting adolescents with Fragile X syndrome (FXS) are advancing, with a FDA Pre-IND interaction expected in mid CY21 which will inform trial commencement, currently expected in CY21. Actinogen was recently awarded Rare Paediatric Disease Designation in FXS which includes priority review and potentially faster clinical development and commercialisation of Xanamem in FXS, as well as a separate, tradeable priority review voucher.

Actinogen continues to focus on various shareholder value drivers through a strong commercialisation strategy, including multiple trials in clinical development and a focus on business development activities. As part of this, Actinogen continues to assess additional opportunities to expand the clinical pipeline beyond Alzheimer's and FXS.

Actinogen's presentation is attached to this announcement.

Teleconference Notification

Conference call details:

Date: Friday, 23 April 2021

Time: 9.00am (AEST)

Registration details

Participants are encouraged to pre-register for the webcast through the link below. Upon registration, participants will receive a unique pin granting fast-track access to the conference call.

<https://s1.c-conf.com/diamondpass/10013510-v1ru5s.html>

If you do not pre-register for the event, you can dial into the event using one of the numbers below. Please dial in five minutes before the webcast begins and provide your name and the participant PIN code.

Participant PIN code: 10013510

Dial-in numbers:

Australia:	1800 455 963	USA/Canada:	1 855 624 0077
New Zealand:	0800 452 795	UK:	0800 051 1453
Singapore:	800 101 2702	Spain:	900 823 322
Hong Kong:	800 968 273	Switzerland:	0800 802 498
Malaysia:	1800 816 441	Other International:	+61 7 3145 4005

A transcript of the conference call will be made available on the ASX in the days following the call.

ENDS

Actinogen Medical

Investor Enquiries

ACTINOGEN MEDICAL LIMITED TRADING AS ACTINOGEN MEDICAL ACN 086 778 476 ASX | ACW

Suite 901, Level 9, 109 Pitt Street, Sydney NSW 2000 AUSTRALIA

TELEPHONE +61 2 8964 7401

WEB www.actinogen.com.au

Dr. Steven Gourlay
CEO & Managing Director
P: +61 2 8964 7401
E: steven.gourlay@actinogen.com.au

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 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.

Disclaimer

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, Link Market Services.



Strategic Update & Investor Presentation

Dr. Steven Gourlay: CEO & MD

April 2021

“*After many years of working in the biopharma industry, I am excited by the huge potential of Actinogen.*

In my last major role at Principia Biopharma as Chief Medical Officer, I steered two small molecules from a microcap company valuation, through successful Phase II development and into Phase III, resulting in a significant value appreciation for shareholders when the company was acquired for US\$3.7B.





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We are now planning for multiple shots on goal and strongly believe the upcoming trials are designed to achieve informative and positive outcomes. I look forward to working with the team to further develop Xanamem as we progress the development pipeline.

- Dr Steven Gourlay, Actinogen CEO / MD”

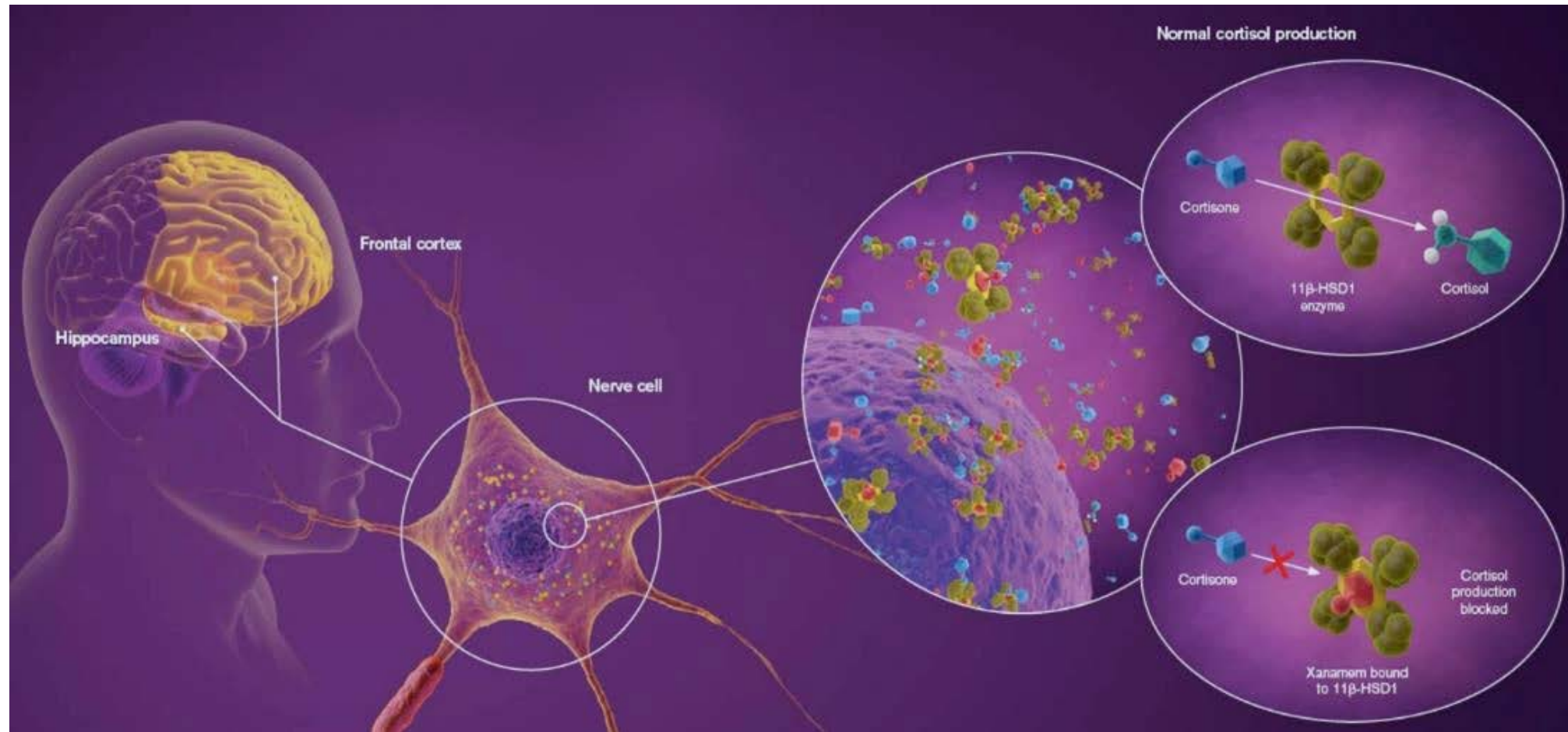
Executive summary

Actinogen Medical (ASX:ACW) is developing a novel treatment to address significant unmet need in a range of central nervous system (CNS) diseases with **rapid onset of clinical activity demonstrated**

 Drug well understood	<ul style="list-style-type: none">▪ Xanamem demonstrated to be a brain penetrant 11β-HSD1 small molecule enzyme inhibitor, that works to safely inhibit excess cortisol production in the brain▪ Favourable drug attributes (e.g. low daily dose, rapid effect, co-administrable, safe) and can be leveraged across multiple indications
 Significant dataset leveraged into clinical pathway	<ul style="list-style-type: none">▪ Phase 1 study demonstrated statistically significant efficacy signals in multiple cognition domains in healthy patients using a modern and sensitive endpoint, which can now be utilised in future studies▪ Human Target Occupancy Study PET data demonstrates consistent suppression of enzyme activity in the brain across a range of doses ("flat dose-response curve") - supporting a low dose of Xanamem
 Advancing multiple near-term clinical trials	<ul style="list-style-type: none">▪ Seeking to confirm minimum effective Xanamem dose (XanaMIA Part A), to inform XanaMIA Part B in patients with Mild Cognitive Impairment due to Alzheimer's disease▪ Phase II trial in patients with Fragile X syndrome (XanaFX), with Rare Paediatric Disease Designation awarded by US FDA
 Strong outlook with significant value upside	<ul style="list-style-type: none">▪ Strong cash balance of ~\$15.2M¹, with planned clinical trials fully funded▪ Clinical trials to commence in CY21, with Actinogen assessing additional indications▪ Targeting value creating opportunities by proactively engaging with potential future partners

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



Xanamem™ - favourable profile across multiple domains

Further clinical development of Xanamem underpinned by attractive characteristics

- ✓ **Rapid clinical effect:** Improved attention and working memory seen as early as 2 weeks after first treatment¹; hormone pharmacodynamic activity maximal at 10mg dose, with high brain PET occupancy at 7 days
- ✓ **Low dose, daily:** Demonstrates high bioavailability with slow clearance supporting low-dose, once daily administration, providing potential compliance and commercial benefits
- ✓ **Brain penetrant:** Effective levels of Xanamem measured in the brain, consistent with human brain PET pharmacodynamic activity shown at doses $\geq 5\text{mg}$
- ✓ **Co-administrable:** Low drug to drug interaction potential; other medications able to be used concurrently with Xanamem
- ✓ **Safety database >200 subjects:** Safety profile demonstrated in multiple human trials

Xanamem is a platform drug and can be leveraged across multiple indications

Key achievements place Actinogen in a strong position going forward



- ✓ Xanamem demonstrates cognitive¹ activity and pharmacodynamic activity (11B-HSD1 inhibition) in preclinical and clinical trials, underpinned by a substantial clinical safety database



- ✓ Xanamem manufacturing process and supply chain optimised to improve commercial viability, and time required for manufacturing

FDA

- ✓ US FDA² granted Rare Paediatric Disease Designation for Fragile X syndrome



- ✓ Well funded, with ~\$15M capital raised in 2020/21 to fully fund multiple phase II trials



- ✓ Comprehensive review of Xanamem dataset and scientific literature, to optimise clinical trial designs and seeking a minimum effective dose


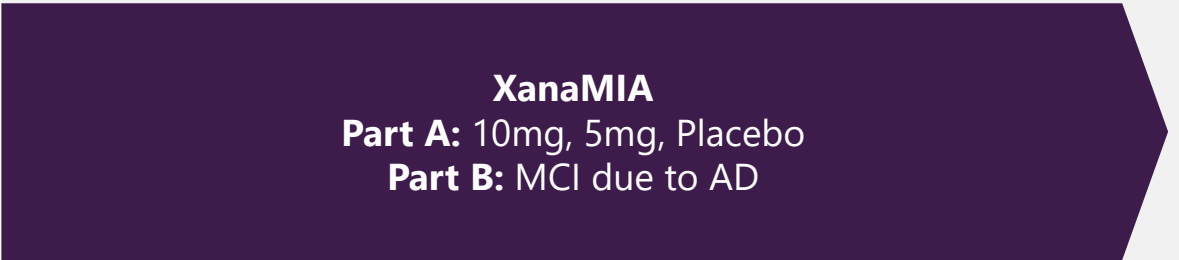




Next steps

Actinogen well placed to commence optimised Phase II clinical trials in the near-term

- Dose ranging study bridging mild cognitive impairment (MCI) due to Alzheimer's disease (AD) trial
- Fragile X syndrome (FXS) trial

Clinical development pathway

Major clinical trials to be initiated in CY21 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 Part A: 10mg, 5mg, Placebo Part B: MCI due to AD</p>	<p><i>Future trials informed by XanaMIA data (with partnership potential)</i></p>
 <p>Anxiety, sleep & behavioural problems in Fragile X syndrome</p>	 <p>FDA Pre-IND Meeting</p> <p>XanaFX 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 target</p> <p>Target indication Phase II trial</p>	

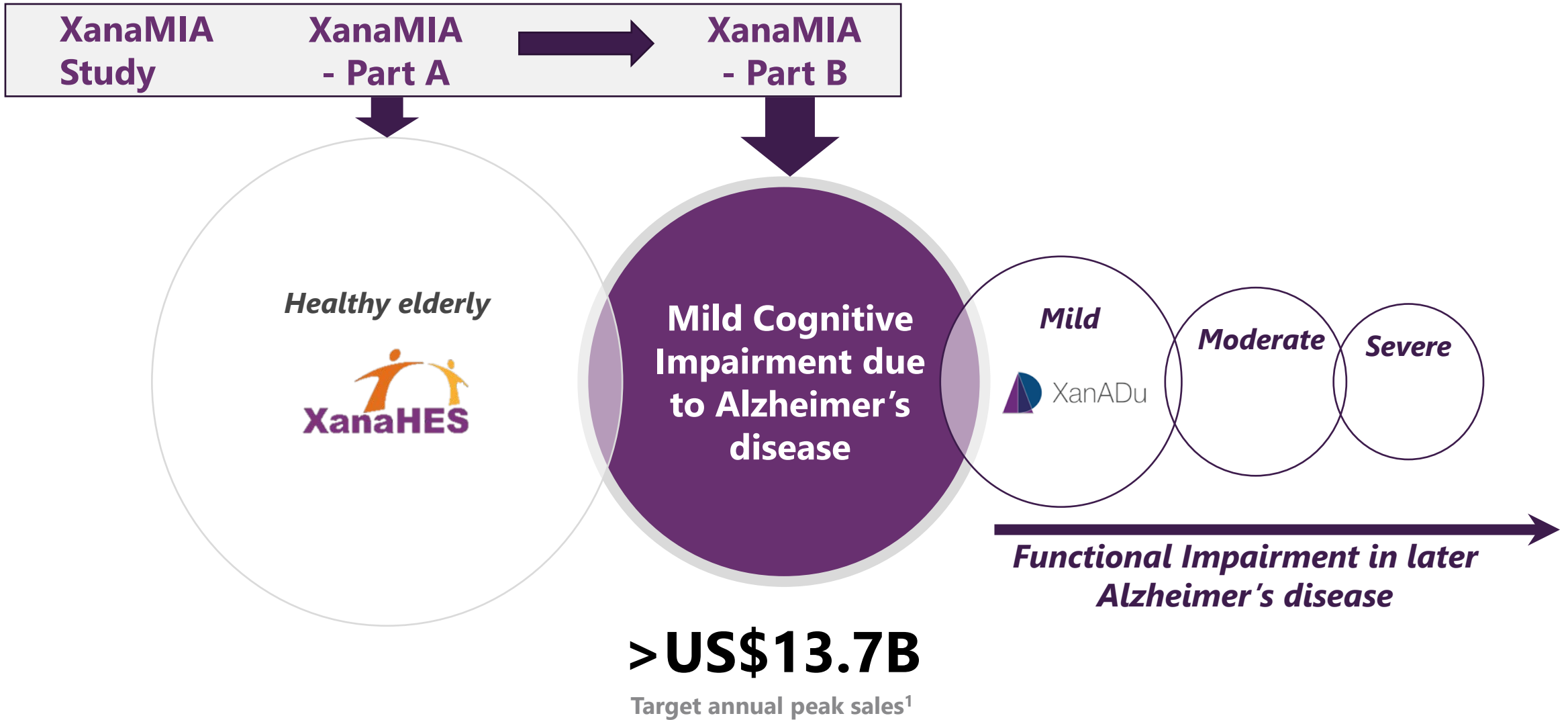


Mild cognitive impairment
due to
Alzheimer's disease





Bridging positive Phase I cognition data to Alzheimer's patients



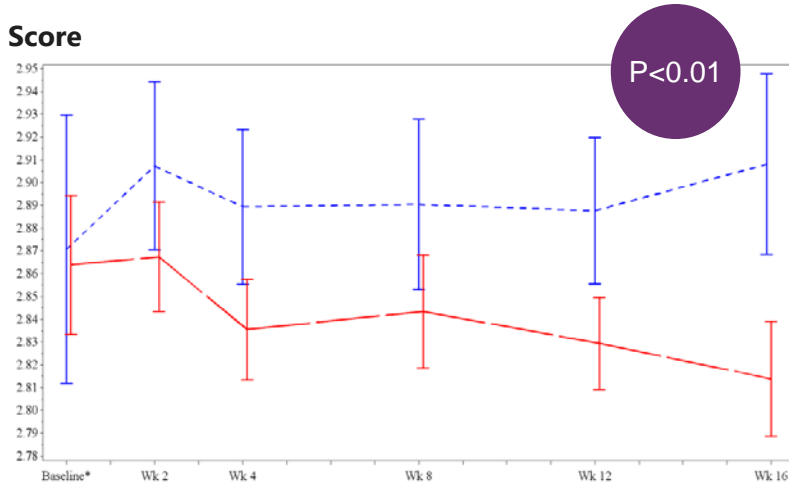


Breakthrough results achieved

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

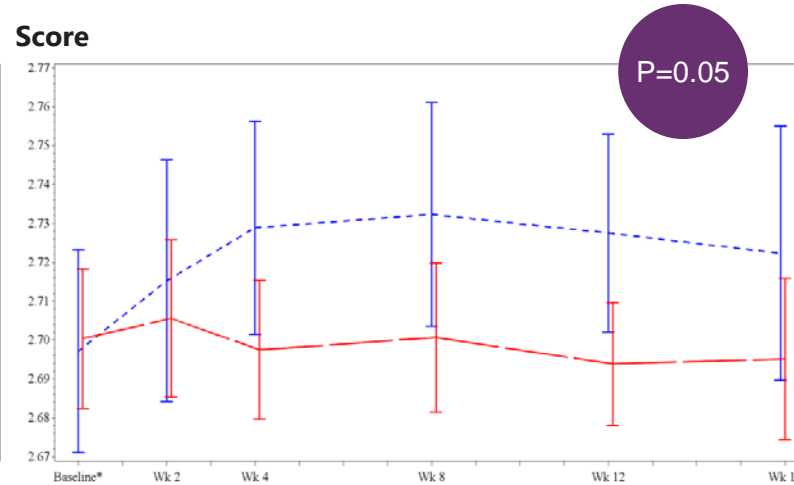
Working memory (One Back Test)

Strongly statistically significant result



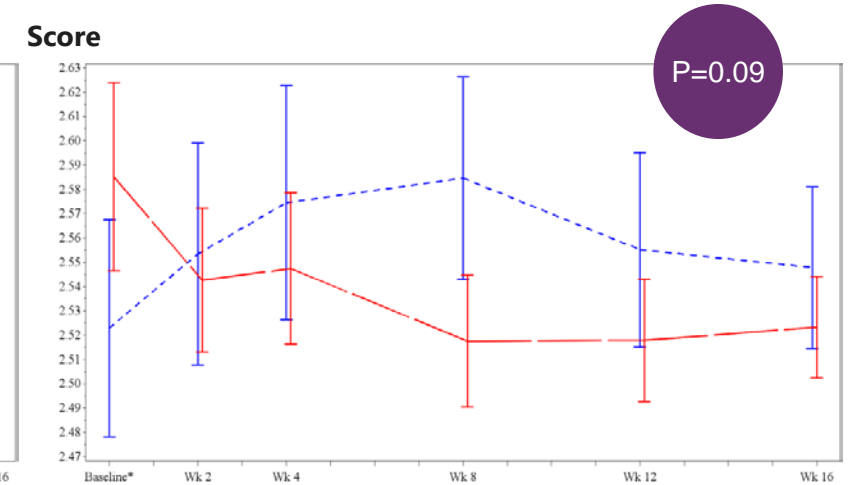
Visual attention (Identification Test)

Statistically significant result



Psychomotor function (Detection Test)

Good trend to a positive result



Treatment Group
 — Xanamem 30pts - - - Placebo 12 pts

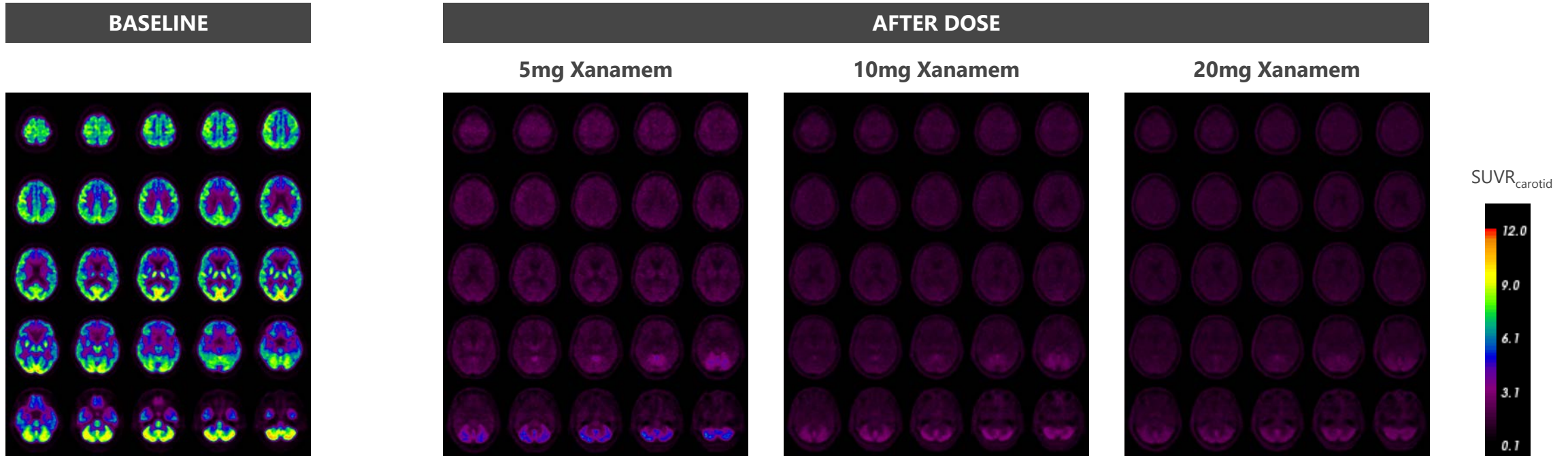
Efficacy results achieved through sensitive and modern testing method which can now be utilised in future studies supported by increasing clinical adoption



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)

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, even a 5mg Xanamem dose.

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

Actinogen is seeking to confirm the minimum effective dose of Xanamem to use going forward.



XanaMIA Phase II trial to commence mid CY21

Targeting the first stage of Alzheimer's disease

XanaMIA - Part A

- **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

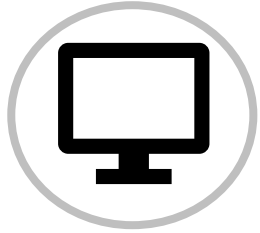
- Targeting subjects with **mild cognitive impairment** due to Alzheimer's disease (using positive serum biomarkers)
- Bridging to patients with **modern and sensitive cognition tests** (Cogstate, iDSST) from Part A
- Introducing other cognitive and functional endpoints that are **accepted by regulators for later studies**: final selection after reanalysis of XanADu trial Alzheimer's data

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



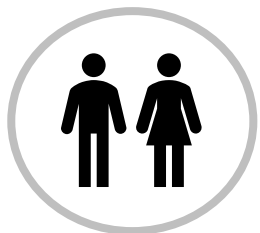
XanaMIA is designed to maximise success

Learnings from the XanaHES and XanADu trials have enabled us to pursue an optimised testing platform



Modern testing capabilities (Cogstate Neurological Test Battery)

- ✓ Highly sensitive computerised test battery measuring memory, attention, and brain processing speed
- ✓ Easily and reproducibly administered on iPad, with clearly defined endpoints
- ✓ Positive data with Xanamem in prior trial and used in other Phase II cognition trials
- ✓ FDA approved¹ digit symbol substitution test (iDSST) included in Cogstate platform - an extra measure of processing speed



Defined patient selection criteria for MCI population

- ✓ Positive serum biomarkers to confirm MCI is related to Alzheimer's disease in each patient
- ✓ Early stage of disease, to ensure each patient does not have functional impairment present in later stages of Alzheimer's disease



Fragile X syndrome

Fragile X is the most common cause of developmental problems including autism and mental retardation



Fragile X syndrome is an attractive opportunity

Fragile X syndrome (FXS) is a rare genetic condition caused by a mutation to the FMR1 gene located on the X chromosome

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 has been awarded **Rare Paediatric Disease Designation**, and is expected to be eligible for Orphan Drug Designation
- Provides attractive regulatory, development, and commercial benefits

Data generation

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

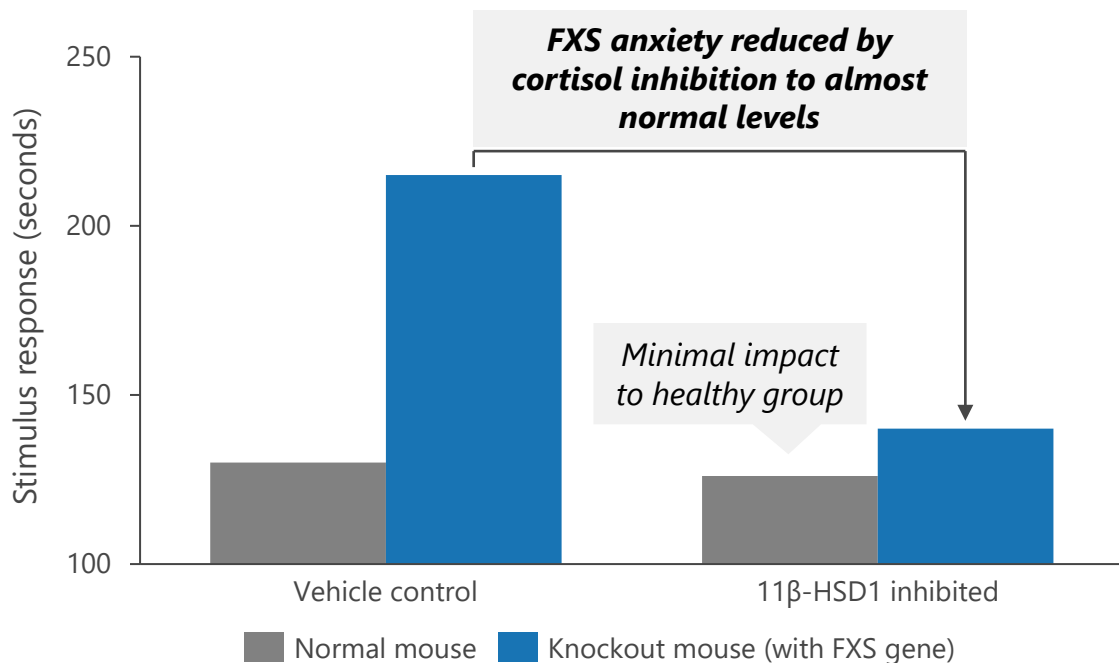
Valuable commercial opportunity¹

- 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)



Strong scientific rationale for Xanamem as a treatment in FXS

Pre-clinical mouse model of Fragile X indicates possible efficacy¹



Symptoms of Fragile X syndrome are all potentially amenable to Xanamem therapy

XanaFX trial target symptoms:



Other FXS symptoms potentially amenable to Xanamem therapy:



Preclinical studies support cortisol inhibition as a potential treatment of anxiety and other symptoms in FXS patients

Anxiety, sleep and behavioural problems in FXS are often associated with raised cortisol; Xanamem MoA (11β-HSD1 of cortisol) has potential to improve symptoms



Recent developments underpinning the Fragile X Phase II trial

FDA designations

- ✓ **Rare Paediatric Disease Designation** (RPDD) received in Feb 2021
- ✓ Priority (6-month) review for Xanamem FX
- ✓ Transferable (including by sale) Priority Review Voucher - if Xanamem is first registered in the US for FXS
- ✓ Orphan Drug Designation potential

Provisional XanaFX design

- Planning for ~30 adolescent males (12-18 years old) with FXS
- Double-blind placebo-controlled trial
- Evaluating safety and efficacy of Xanamem on dimensions of anxiety, sleep, attention and behavioural problems

Key upcoming milestones



Pre-IND feedback mid CY21



XanaFX trial to **commence H2 CY21**



Top line data expected end CY22



Outlook

Significant value upside for Actinogen

Accelerate clinical development

- Expand pipeline with additional indications and clinical trials, providing multiple shots on goal
- Generate data to optimise potential partnership discussions
- Scale up and optimise manufacturing to prepare for commercially viable, large scale production

Potential commercial & corporate value



Big Pharma engagement

- Actinogen actively engaging with potential future partners on a regular basis
- High level of commercial interest and deal flow
- Recent AD deal value of ~US\$1B (US\$160M - US\$2.4B range)¹

RPDD

Transferable PRV voucher

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



High company valuations

- Companies with a lead asset in phase II or III development for AD have valuations between ~US\$350M-\$1.4B⁴

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 Xanamem 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: 292 euro / ~US\$350m); Athira Pharma, phase II AD lead asset (NASDAQ GS:US\$610m); Cortexyme, phase III AD lead asset (NASDAQ GS:US\$1.1B) and same drug in phase II for periodontal disease and Parkinson's disease; Cassava Sciences, AD lead asset phase III-ready (NASDAQ GS:US\$1.41B). All companies' value primarily attributed to their lead AD asset. Market capitalisations as of 16/4/2021.

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 H1 2022
- XanaFX data expected by early 2023
- XanaMIA Part B data expected 2023

Pursue other high priority indications

- Leverage strong academic, grant collaborations

Expand team to pursue aggressive timelines

Publications and scientific presentations



The background of the slide features a close-up, slightly blurred photograph of laboratory glassware. In the foreground, a pipette is positioned over a test tube, with a single drop of liquid about to fall. Behind it, another test tube is visible, and further back, a larger beaker or flask. The entire scene is bathed in a deep purple light, creating a professional and scientific atmosphere.

Appendix

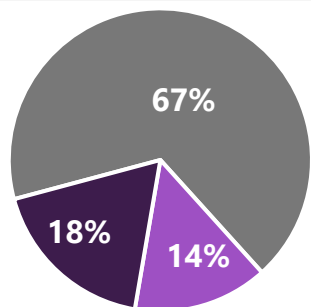
Corporate overview

Trading Information

52 week high	A\$0.062
52 week low	A\$0.018
Number of shares	1,660.6M
Market capitalisation (20 April 2021)	A\$99.6M
Net cash ¹	A\$15.2M

Major Shareholders

BVF Partners	14.4%
Steven Gourlay ³	3.8%
Edinburgh Technology Fund	2.9%



Share Price Performance² (YTD)



Source: IRESS

1. Cash as at 31 March 2021

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

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

Strong Leadership and Management

Leadership has a strong track record in drug development and extensive 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 Venture Partners



Dr. Steven Gourlay
CEO & MD

MBBS; PhD; MBA



- **30+ years experience** in the development of novel therapeutics and has significant regulatory experience interacting with FDA and EMA
- Formerly the founding Chief Medical Officer at US-based Principia Biopharma Inc., and Senior Director of Genentech

...with a talented management team in place



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; Former Senior VP and CMO at Amgen



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



Miriam Roesner
Clinical development manager

BASc



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; formerly senior leadership roles in investment banking

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

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

Scientific Advisory Board

Combining deep understanding of endocrinology, 11 β -HSD1 and drug discovery



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 this work through various awards



Prof. Alan Boyd

- **30+ years experience** in the pharmaceutical industry, with senior management roles
- Experience supporting early-stage life-science companies through Boyd Consultants
- Faculty of Pharmaceutical Medicine President, Royal College of Physicians, UK



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



Disclaimer

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