

ASX ANNOUNCEMENT

AGM Presentations

Sydney, 10 November 2021. Actinogen Medical ASX:ACW ("ACW" or "the Company") is pleased to attach the Chair's Address and CEO's presentation to be presented at today's Annual General Meeting which will be held virtually commencing at 11.00 am (AEDT).

ENDS

Dr. Steven Gourlay CEO & Managing Director P: +61 2 8964 7401

Investors Michael Roberts Investor Relations P: +61 2 8964 7401

Media Randal Killip Profile for Media M: +61 425 714 159

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 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.

Cognitive function means how a person understands, remembers and thinks clearly. Cognitive functions include memory, reasoning, awareness and decision-making, and to a large extent, influence our personality.

We are currently developing our lead compound, Xanamem®, as a promising new therapy for Alzheimer's Disease, Fragile X Syndrome, and other neurological diseases where reducing cortisol inside brain cells could have a positive impact. 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 works by blocking the production of intracellular cortisol through the inhibition of the 11β-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, potentially linked to cognitive impairment and anxiety in Fragile X Syndrome, and cognitive impairment in other diseases.

The Company has studied 11β-HSD1 inhibition by Xanamem in more than 250 volunteers and patients, so far finding a statistically significant improvement in cognition over placebo in healthy, older volunteers. A series of Phase 2 studies in multiple diseases is being conducted to further confirm and characterise 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.

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, AUTOMIC GROUP.



10 November 2021

ACW 2021 AGM Chair's Address

On behalf of the Board of Directors and staff of Actinogen Medical Ltd, I welcome you to our 2021 Annual General Meeting. I am pleased to report that Actinogen has managed to do well through the 2021 financial year, despite the COVID-19 pandemic, which has challenged the resilience of the healthcare industry, in particular for Actinogen as restrictions have affected the progress of clinical development worldwide.

Fortunately, with limited impediment to our operating progress, we have successfully executed our clinical pipeline objectives and the future of the Company remains extremely bright.

While the pandemic has forced us to conduct this AGM as a virtual meeting, it is pleasing to see that we are well-placed to emerge from the pandemic environment in a strong commercial and operating position for 2022 and beyond, driven by our corporate strategy and underpinned by the support of our shareholders.

As a highlight for the year, in March, Dr. Steven Gourlay joined us as Chief Executive Officer and Managing Director, following three months acquainting himself with the Company as our Consultant Chief Medical Officer. Steve brings a wealth of experience in the clinical development of novel small-molecule therapies, with an accomplished record of advancing several molecules from the preclinical stage to Phase 3, then on to approval and commercialisation.

Since taking the role, Steve has been proactive in developing and setting the Company's strategy with the Board, as well as building our stellar team to help optimise Actinogen's clinical development pipeline. The Board is delighted by Steve's eagerness, commitment and immediate impact, whilst his appointment has met with shareholder enthusiasm and broader market approval. We look forward to seeing the Company continuing to grow and prosper under Steve's leadership.

I don't mind pointing out that under Steve's guidance, the Actinogen share price has risen more than fivefold. It greatly pleases me that, at last, the Company is trading well above all prices that it has raised funds at in its past.

Turning to the balance sheet, Actinogen remains in a strong financial position with \$11.8 million in cash as at 30 September 2021, sufficient to fund our currently planned phase 2 clinical trials. We added a further \$1.4 million in cash in mid-October through the receipt of an R&D tax incentive refund.

In the middle of the financial year, in order to advance our clinical development pipeline, we completed a capital raising program exceeding \$10.9 million. The Board was extremely pleased with the support received from both new and current investors, which has helped strengthen our financial position and allows us to implement certain strategic priorities.

On corporate governance matters, your Board continually seeks improvement in its governance and management oversight capability. During the past year, we conducted our periodic review of all activities and responsibilities, including the annual Board skills matrix to identify gaps and opportunities for improvement.

In saying that:

We will continue to assess the skills suitable for the Board and when appropriate, make changes and or

additions to its composition.

Subsequent to the end of the financial year we established an inaugural audit sub-committee to, among

several responsibilities, monitor and review the integrity of the Company's financial reporting. In line with

best practice corporate governance, the committee is comprised of independent non-executive directors,

including committee chair Malcolm McComas. The new committee charter is available on our website

along with other corporate governance policies including the main board charter.

I also would like to take this opportunity to express our sincere thanks to Dr Bill Ketelbey for his valued

contribution and executive leadership as CEO and Managing Director of the Company during the six years

to February 2021. We wish Bill health and success in the future.

In conclusion, I would like to thank our dedicated and diligent leadership team, staff, consultant advisors and

business partner organisations, who all contribute to the Company's operational excellence and success.

I also wish to thank my fellow Board members for their ongoing commitment to Actinogen Medical.

Actinogen has just completed a very active, achievement-filled 2021 financial year. The Board is confident

about the Company's prospects and capability to build on that success under the leadership of our new CEO

and his team. We will continue to proactively manage and drive excellence in our operations, such that we

execute the Company's strategic priorities, thus maximising value in the best interests of our shareholders. We will do this at the same time as providing hope for sufferers of conditions like Alzheimer's Disease and

Fragile X Syndrome.

Lastly, I would like to thank all of our Actinogen shareholders for their ongoing support and we look forward

to updating you on our further progress during the year.

Dr Geoff Brooke Chair

ENDS

Dr. Steven Gourlay CEO & Managing Director

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About Actinogen Medical

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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 approximately 300 volunteers and patients, finding a statistically significant improvement in cognition over placebo in healthy, older volunteers. A series of Phase 2 studies in multiple indications will be conducted to further confirm and characterise Xanamem's efficacy and safety.

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CEO's presentation

Dr. Steven Gourlay MBBS PhD MBA: CEO & MD, CMO

10 November 2021



Disclaimer

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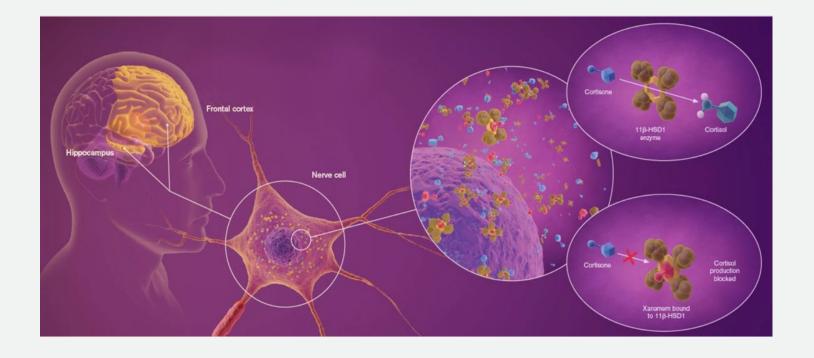


Actinogen is a neurotherapeutics developer realising a revolutionary therapy so neurology patients can live their best lives



Xanamem: oral treatment and novel mechanism

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



^{1.} Xanamem® is a CNS (Central Nervous System) penetrant small molecule based on human PET evidence and 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



Actinogen snapshot

Actinogen Medical (ASX:ACW) is developing a novel oral treatment with rapid onset of clinical activity to address a range of central nervous system (CNS) diseases



Favourable pharmaceutical properties



Substantial clinical data



Attractive first target indications and rationale



Protected and funded

- Demonstrated target engagement in brain and HPA axis in human trials
- ✓ Low dose, ≤10mg
- Low drug-drug interaction potential
- √ >250 subjects or patients safely treated
- ✓ Large Phase 2 safety database with 12 weeks therapy (N=185).
- ✓ Cognitive enhancement activity shown in healthy older volunteers
- Strong cortisol rationale for treatment of early stages of Alzheimer's Disease
- ✓ Strong cortisol rationale for multiple symptom domains of Fragile X Syndrome
- Strong cortisol rationale for multiple other indications
- Molecule in-licensed from U Edinburgh in 2014
- Comprehensive patents in place¹
- Cash A\$11.8M at 30 Sep 2021 plus A\$1.4M R&D Tax Incentive rebate Oct 2021



Strong Leadership and Management

Extensive drug development and commercial experience

Experienced Board of Directors...



Dr. Geoff Brooke Chair MBBS: MBA







 Founder and MD of Medvest Inc and GBS Ventures, Chair of Cynata Therapeutics, Board Member of Acrux



Dr. George Morstyn Non-Executive DirectorMBBS; PhD; FRACP; MAICD





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

...with a talented management team in place



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/ourcompany/#about-us



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



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



Therese Russell
Head of People &
Infrastructure



Dr Christian Toouli

Head of Business
Development

PhD; GAICD



Esteemed Advisory Boards

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

Xanamem Clinical Advisory Board

Deeply experienced in Alzheimer's Disease drug development



Prof. Craig Ritchie
Chair



THE UNIVERSITY
of EDINBURGH

- 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

Scientific Advisory Board

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





Prof. Jonathan Seckl Prof. Brian Walker



- 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)



- 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



of EDINBURGH

- Chair of Medicines at the Centre of Cardiovascular Science, University of Edinburgh
- Former positions across both biotech and academia

Prof. Scott Webster

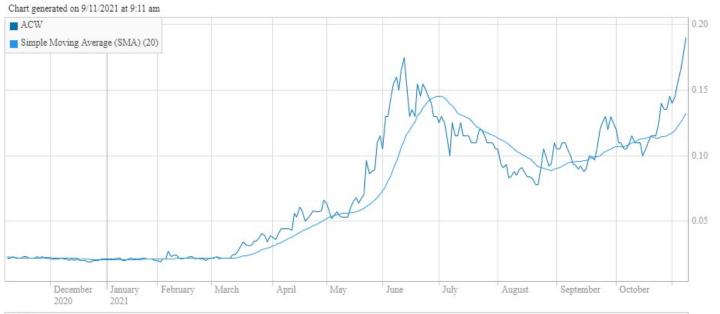
 Founder and Chief Scientific Officer at Kynos Therapeutics

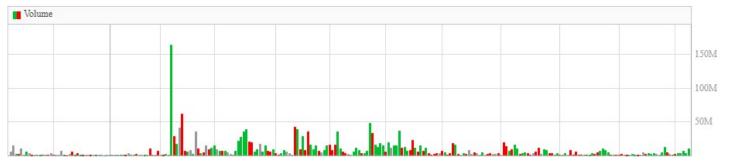
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ACW stock performance 12 months



Share price chart at 9 Nov 2021



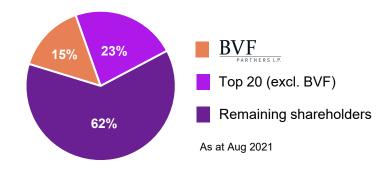


Trading Information

52 week high	A\$0.20
52 week low	A\$0.02
Number of shares	1,660.6M
Market capitalisation (9 Nov 2021)	A\$315M
Net cash at 30 Sep ¹	A\$11.8M

Major Shareholders

BVF Partners	14.9%
Steven Gourlay	3.8%
Edinburgh Technology Fund	2.9%





Xanamem Clinical Development Pipeline

Diseases to be studied in 2021/2022	Phase 2 Pathway	Outlook
Mild cognitive impairment due to Alzheimer's disease	XanaMIA Part A: 10mg, 5mg, Placebo Older Volunteers: cognition Part B: Patients with MCI due to AD: cognition & biomarkers	"Big-to-market" Multiple Phase 2b/3 trials
Anxiety, sleep & behavioural problems in Fragile X Syndrome	FDA Pre-IND Meeting XanaFX Phase 2 trial	"Fast-to-market" single pivotal Phase 3
Third neurological disease to be announced	Study yereparation XanaXX Phase 2 randomised trial	Designed to facilitate optionality for portfolio





Status: Analysis

Alzheimer's Disease

Targeting cognitive enhancement and disease modification in the early stages of disease

Science Behind the Xanamem AD Program

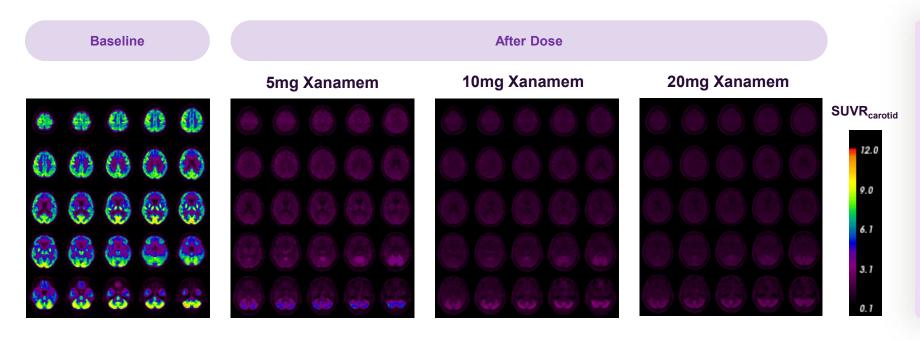
- ✓ Cortisol is toxic to monkey brain cells¹
- ✓ Cortisol impairs animal cognition²
- ✓ Cortisol & hippocampal volume/memory³
- ✓ Higher blood cortisol & cognitive decline⁴
- ✓ Higher CSF cortisol & cognitive decline⁵
- √ 11β-HSD1 Alzheimer's mouse model⁶
- ✓ Xanamem & improved human cognition⁷

- 1. Implant in hippocampus, Sapolsky et al. 1990; increased amyloid proteins, Green et al. 2006
- 2. Literature review. Ouanes et al. 2019
- 3. Human study with MRI and cognitive assessment, Lupien et al. 1998
- 4. Morning cortisol & cognitive decline, Cernansky et al. 2006; Pietrzak et al. 2017
- 5. Longitudinal human study with multivariate modelling, Popp et al. 2015
- 6. 11β -HSD1 inhibition reduced amyloid and cognitive decline, Sooy at al. 2015
- 7. Xanamem placebo-controlled trial working memory & attention (Actinogen data on file)





PET data supports a low Xanamem dose ≤10mg daily



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

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

Note: Study population consisted of ~50% healthy subjects (cognitively normal) and ~50% with Alzheimer's disease. Subjects dosed for seven days. Baseline: Mean of baseline scans of patients in that dose group; After dose: Mean of post-dosing (7 days) scans in that dose group.

.



Cognitive improvement demonstrated

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



Large effect sizes seen in working memory and attention, trends in other domains

Working memory (One Back Test)

Strongly statistically significant result

Visual attention (Identification Test)
Statistically significant result

Psychomotor function (Detection Test)

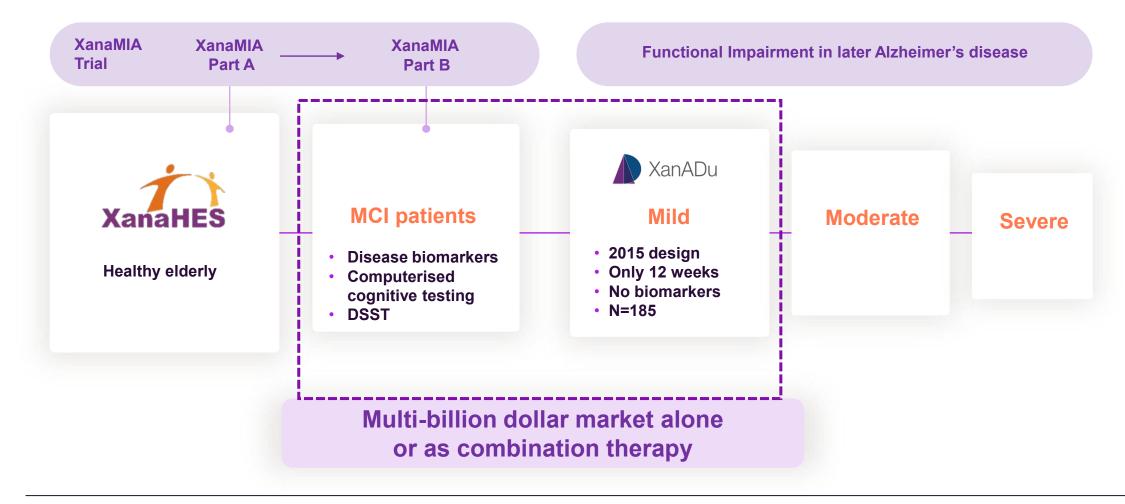
Good trend to a positive result

^{1.} XanaHES Phase 1 clinical trial treated healthy elderly patients with 20mg Xanamem daily (n=30 active, n=12 placebo). 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.













XanaMIA Phase 1b/2 trial data in 2022 & 2023

Targeting the first stages of Alzheimer's Disease

XanaMIA - Part A

H12022: minimum effective dose on cognition

- Healthy older subjects with normal cognition,
 ≥50 years of age (same as XanaHES trial)
- Sensitive endpoints and testing criteria highly sensitive cognition tests (Cogstate, iDSST)
- DSST used for vortioxetine regulatory cognitive claim
- Dose ranging 5mg, 10mg vs. placebo

XanaMIA - Part B

2023: disease-modifying potential on biomarkers

- Targeting subjects with mild cognitive impairment due to Alzheimer's disease (using positive serum biomarkers)
- Measuring disease-modifying potential with change in Alzheimer's Disease biomarkers
- One or more doses depending on Part A





Fragile X Syndrome

An inherited disorder caused by the FMR1 mutation on the X chromosome with no approved treatments





Fragile X Syndrome has high unmet medical need



Unmet medical need



Strategic benefits



Fast-to-market path



Valuable commercial opportunity¹

- Commonest genetic cause of intellectual disability, predominantly males
- Management of FXS is often complex, with life-long treatment required for patients
- Xanamem in FXS has been awarded Rare Paediatric Disease Designation, and eligible for Orphan Drug Designation
- Broadens range of partners in orphan space
- Moderate sized, comprehensive proof-of-concept Phase 2
- Anticipate single Phase 3 for approval
- Estimated global market size of ~US\$250M
- Related indications such as Autism Spectrum Disorder
- Priority Review Voucher value ~US\$100-125M

Science Behind the Xanamem FXS Program

- ✓ Elevated blood cortisol in patients¹
- ✓ Elevated cortisol & human symptoms²
- ✓ Glutamate linked to cortisol response³
- ✓ FMR1 KO mice show raised cortisol⁴
- ✓ Elevated 11β-HSD1 in FXS mouse⁵
- √ 11β-HSD1 Fragile X mouse model⁶

- 1. Hessl et al. 2002; Wisbeck et al. 2000
- 2. Elevated cortisol correlates with symptoms, Hessl et al. 2002; Hardiman & Bratt 2016
- 3. Mouse FMR1 mutation model of Fragile X & glutamate, cortisol mechanism Ghilian et al. 2015
- 4. Mouse cortisol (corticosterone), Lauterborn et al. 2004
- 5. FMR1 deficiency promotes age-dependent alterations in the cortical synaptic proteome, Tang et al., 2015
- 6. Normalisation of anxiety with 11β-HSD1 inhibition, Vanderklish & Francesconi 2019

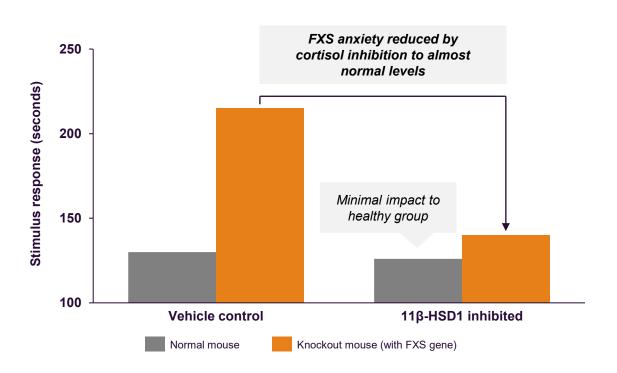




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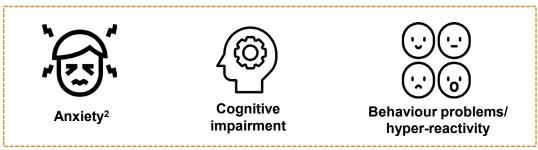
Xanamem may treat multiple symptom domains in FXS

Normalisation of anxiety in the FXS KO mouse¹



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

XanaFX trial target symptoms



Other FXS symptoms potentially amenable to Xanamem therapy



Pre-clinical FMR1 knock-out mouse model using BVT 2733 as the 11β-HSD1 inhibitor showed highly significant results (***p<0.0001). Normal mouse is a wild-type mouse. (Source: Vanderklish PW. 2019. Compounds for treatment of emotional/psychological symptoms in fragile x syndrome, WO 2019/075394 Al.)







Significant value upside for Actinogen

Accelerate clinical development

- Commence Fragile X Syndrome trial
- Expand pipeline with third Phase 2 program
- Create optionality for development and partnerships

Forward planning

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

Value from partnerships, peer companies



Pharma/biotech engagement

Actively engaging with large and mid-size potential partners



Priority review and PR voucher

- Priority review granted by FDA
- PRVs recently traded for US\$100M-US\$125M



High peer AD company valuations suggest near term growth potential

 Peer companies in phase 2 or 3 for AD: valuations ~US\$250M-\$3.4B¹

^{1.} Vivoryon Therapeutics, phase 2a/b AD lead asset (EURONEXT Amsterdam: 408 euro / ~US\$500m); Athira Pharma, phase 2 AD lead asset (NASDAQ GS:~US\$583m); Cortexyme, phase 2b/3 AD lead asset (NASDAQ GS:~US\$490m) and same drug in phase II for periodontal disease and Parkinson's disease; Cassava Sciences, AD lead asset phase 2 asset (NASDAQ GS:~US3.4B); Annovis Bio, early phase 2 data AD, PD (NASDAQ US\$249m). All companies' value primarily attributed to their lead AD asset. Market capitalisations as of November 5 2021.

Next steps and key catalysts

☐ Clinical trials to read out in 2022 and 2023 XanaMIA

- Part A cognition data H1 2022
- First disease biomarker data possible H2 2022
- Part B patient biomarker/cognition data 2023

XanaFX

o Commencing in 2021, results 2023

□ Pursue other high priority indications

- Announce third disease Phase 2 program 2021, results 2023
- Leverage academic, grant collaborations

□ Publications and scientific presentations

Focus on PET and other peer-review publications

