ASX ANNOUNCEMENT

Actinogen to initiate XanaFX clinical trial in Fragile X syndrome

- The **XanaFX** study will evaluate Xanamem's effect on core symptoms associated with Fragile X syndrome (FXS): **behavioural problems, anxiety, and sleep**
- FXS represents a **compelling therapeutic and commercial opportunity** to address an important unmet medical need with a **significant market opportunity**
- Xanamem in FXS potentially meets the criteria for **Orphan Drug Designation** and **Rare Paediatric Disease Designation**, which could provide attractive regulatory, development, and commercial opportunities
- Actinogen has **partnered with a world class team at Murdoch Children's Research Institute on XanaFX** - the phase II study is expected to commence in 1H CY21
- Broadening the development pipeline strategically **enhances the value and opportunities for Xanamem**, with the new XanaFX study complementing development plans in other disease indications

Sydney, 2 November 2020. Actinogen Medical ASX: ACW ('ACW' or 'the Company') is pleased to provide further details on its recent announcements on the clinical development of Xanamem in **Fragile X syndrome (FXS),** and the upcoming phase II clinical trial **XanaFX ('Xanamem in Fragile X')** in male adolescent FXS patients**.** XanaFX is a trial of its lead drug candidate, Xanamem, in the treatment of the core symptoms associated with FXS: **behavioural problems, anxiety, and sleep.**

A presentation providing an overview of FXS and the unmet medical need, an outline of the XanaFX clinical trial and the strategic rationale for developing Xanamem in this indication, is attached to this announcement.

New indication: Core symptoms associated with FXS (behavioural problems, anxiety, and sleep)

Selection of FXS follows significant clinical interest in evaluating Xanamem across a range of medical conditions associated with raised cortisol.

FXS is a rare genetic disorder characterised by a range of developmental problems, including learning disabilities, behavioural problems including autism features, cognitive impairment, speech and language deficits, sleep issues, anxiety and severe difficulties with regulating stress and emotions. Severe anxiety is particularly problematic in FXS and is experienced by approximately 90% of patients. Additionally, the behavioural anomalies and anxiety associated with FXS have a significant impact on the daily lives of FXS patients and those who care for them. Following FXS diagnosis, which typically occurs around three years of age, life-long treatment is often required for the patient. Currently, there are no approved treatment options for FXS.

Multiple pre-clinical and clinical studies have demonstrated links between raised cortisol and many of the symptoms associated with FXS. Significantly, raised cortisol is associated with cognitive impairment and behavioural problems including social anxiety, hyperactivity and social withdrawal in this patient population; representing an opportunity for Xanamem to potentially address this major unmet medical need. The pharmacological properties of Xanamem and the current understanding of FXS pathology strongly supports Xanamem as a potential treatment given its specific mechanism of action of inhibiting excess cortisol production in the brain.

The commercial and strategic opportunities for Xanamem in the treatment of FXS are considerable. Although FXS is a rare disorder, affecting approximately 1 in 2500-4000 males and 1 in 7000-8000 females globally,

anxiety and behavioural problems in FXS patients present a substantial unmet medical need and market opportunity. The FXS market is expected to reach ~US$250m per annum by 2026.

Potential for Orphan Drug Designation / Rare Paediatric Disease Designation

In addition to market and partnering opportunities, Xanamem in FXS has the potential to be granted **Orphan Drug Designation** from the US Food and Drug Administration (FDA) and other major regulatory authorities. Orphan Drug Designation provides multiple incentives for companies whose drug candidates demonstrate potential in the treatment of rare diseases. These incentives include attractive developmental, regulatory, and commercial advantages, allowing drug candidates priority review and rapid advancement to market. Additional incentives include lessened development and regulatory costs and timelines, and greater competitive protection through regulatory exclusivity. In the USA, orphan drugs that qualify for **Rare Paediatric Disease Designation**, which could include Xanamem**,** may also receive a **Priority Review Voucher** from the FDA upon marketing authorisation, which is tradeable and hence comes with its own substantial commercial value. In recent years, biopharma companies have sold Priority Review Vouchers to other pharmaceutical companies for an average of US$133m.

Actinogen partners with Murdoch Children's Research Institute (MCRI) for XanaFX

XanaFX is a Phase II proof-of-concept study, planned for commencement in 1H 2021 at the Murdoch Children's Research Institute (MCRI) and the Royal Children's Hospital in Melbourne. The MCRI team of investigators are world leaders in Fragile X research and have considerable expertise in paediatric clinical trials and natural history studies in FXS and other rare neurodevelopmental disorders. The team includes **A/Prof. David Godler**, **Prof. David Amor, Prof. Noel Cranswick, Prof. Katrina Williams**, **A/Prof. Mathew Hunter and Dr Emma Baker.** The impressive bibliographic details of the team are provided in the attached presentation.

As far as the Company is aware, XanaFX will be the first study to target cortisol inhibition as a treatment for behavioural problems, anxiety, and sleep issues in FXS patients, representing a new and innovative approach with a strong scientific rationale. The primary endpoint is to confirm that Xanamem is safe and well tolerated in a population of male adolescent FXS patients. Secondary endpoints aim to determine if Xanamem improves behavioural problems including communication, socialisation, and daily living skills, as well as anxiety and sleep. The XanaFX study is **fully funded.**

Corporate update: FXS complements broader development portfolio

Actinogen continues to expand upon its previously announced clinical development strategy of targeting a portfolio of disease indications associated with chronically raised cortisol. The additional disease indications being targeted by the Company reflect the substantial pipeline of opportunities presented with Xanamem and include cognitive impairment associated with both schizophrenia and diabetes. The new study in FXS complements this broad portfolio and reflects the breadth of development opportunities for Xanamem across a range of medical conditions, presenting with a high unmet medical need and significant market potential.

To learn more about Xanamem in FXS, please visit: https://actinogen.com.au/fragile-x-syndrome/

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Announcement authorised by the Board of Directors of Actinogen Medical

About Murdoch Children's Research Institute (MCRI)
MCRI is the largest child health research institute in Australia and one of the top three worldwide for research quality and impact. The institute has made over 100 genetic discoveries, led the development of national and international genomic alliances, and is home to Australia's leading paediatric clinical trials centre, Melbourne Children's Trials Centre (MCTC). MCTC currently oversees more than 70 active clinical trials in all phases of drug development, and in a wide range of indications – and a such is one of the largest clinical trials centres in Australia specialising in paediatric disorders.

About Actinogen Medical
Actinogen Medical (ASX:ACW) is an ASX-listed biotechnology company developing novel therapies for neurological, psychiatric and metabolic diseases associated with chronically elevated cortisol. The company is currently developing its lead compound, Xanamem, as a promising new therapy for Alzheimer's disease, Fragile X syndrome, schizophrenia and diabetes. The cognitive dysfunction, behavioural abnormalities, and neuropsychological burden associated with these conditions is significantly debilitating for patients, and there is a substantial unmet medical need for new and improved treatments.

About Xanamem™
Xanamem's novel mechanism of action works by blocking the production of intracellular cortisol – the stress hormone – through the inhibition of the 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 11β-HSD1 enzyme is particularly highly concentrated in the hippocampus and frontal cortex, areas of the brain impacted by a number of diseases and disorders, including Alzheimer's disease, Fragile X syndrome, schizophrenia, diabetes and other conditions associated with chronically raised cortisol.

The Company's XanaHES Phase I trial exploring the safety and tolerability of Xanamem 20mg once daily in healthy elderly volunteers, confirmed the drug's safety profile with no treatment-related serious adverse events. Additionally, the trial demonstrated that Xanamem produced a statistically significant improvement in cognition over placebo, which, along with other recently generated data, confirms 11β-HSD1 inhibition by Xanamem as a promising potential treatment for cognitive impairment associated with raised cortisol.

The Company plans to initiate Phase II studies of Xanamem in various disease areas in 2021, including MCI due to Alzheimer's disease, and Fragile X syndrome.

Xanamem is an investigational product and is not approved for use outside of a clinical trial by the FDA or by any global regulatory authority.

Xanamem™ is a trademark of Actinogen Medical.

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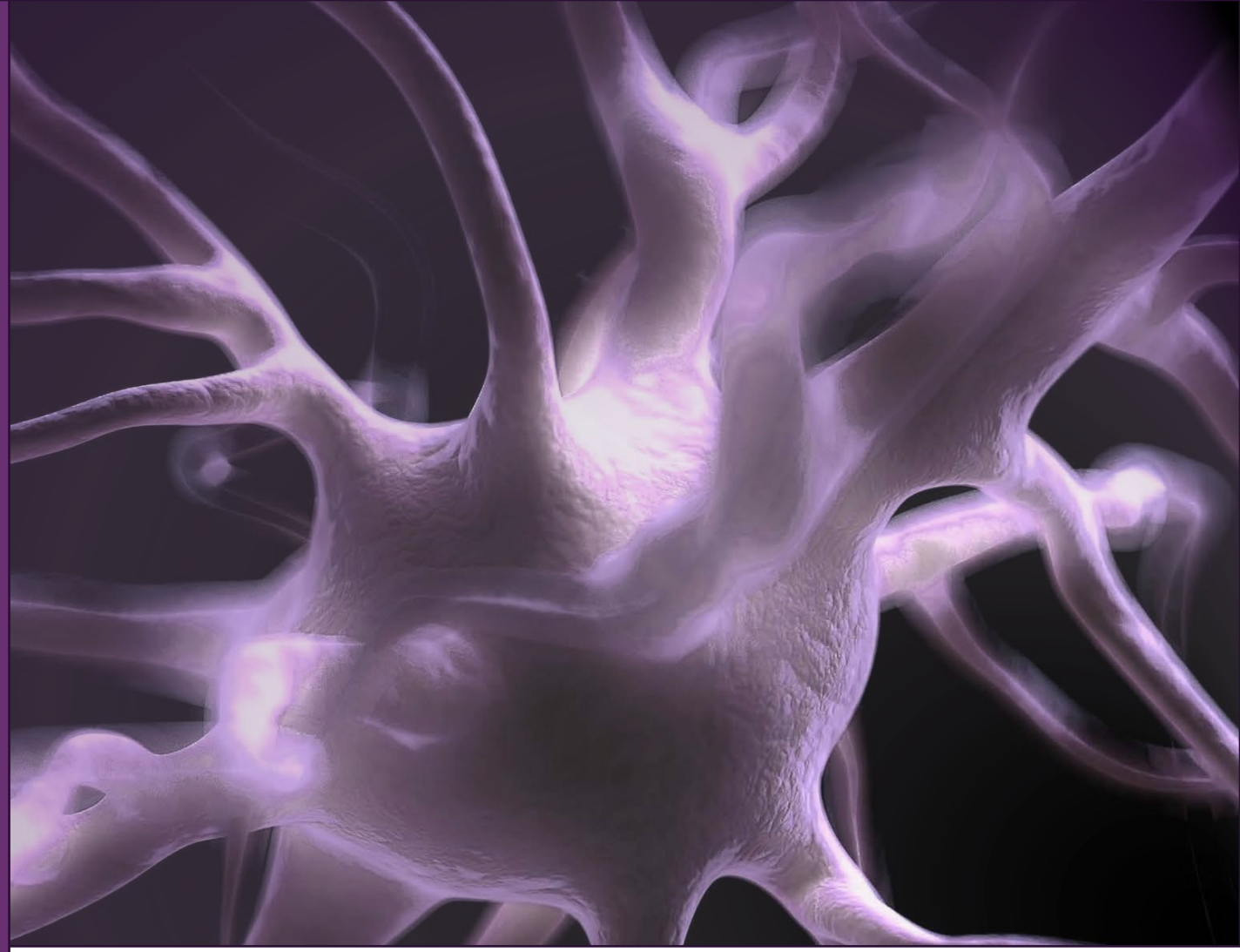
New clinical development opportunity:

Fragile X syndrome



Dr. Bill Ketelbey: CEO & MD

November 2020

Developing novel therapies for cognitive impairment and neuropsychological symptoms due to raised cortisol in a range of chronic diseases

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Executive summary

Behavioural problems, anxiety, and sleep issues in Fragile X syndrome (FXS) selected as the next development opportunity for Xanamem™

Novel therapeutic treatment	▪ Actinogen's lead drug Xanamem is an oral, brain penetrant, selective and effective inhibitor of the 11β-HSD1 enzyme, with a validated novel mechanism of action and strong safety profile ▪ Xanamem has shown to safely and effectively inhibit cortisol production ▪ Xanamem is in development as a treatment for conditions associated with chronically elevated cortisol, including cognitive impairment
Targeting an unmet medical need	▪ FXS is a rare, serious, life-long genetic condition often associated with behavioural problems and anxiety ▪ Anxiety affects ~90% of FXS patients ▪ Limited treatments available for anxiety and behavioural problems associated with FXS – a significant unmet need ▪ Medical research validates Xanamem as a potential treatment, with **raised cortisol in FXS associated with stress-induced behavioural problems**
Compelling strategic & commercial opportunities	▪ FXS represents a commercially valuable market opportunity, with additional significant strategic benefits ▪ Potential for **Orphan Drug Designation** and **Rare Paediatric Disease Designation** provides attractive regulatory, development, and commercial advantages (including potential increased speed to market) ▪ Precedent partnership deals in FXS and potential lucrative FDA **Priority Review Voucher** eligibility
Development plan	▪ **XanaFX**: A Phase II proof-of-concept study, **fully funded and expected to commence in 1H CY21** with completion expected within 12 months[1] ▪ XanaFX study will be conducted in partnership with the **Murdoch Children's Research Institute (MCRI)**

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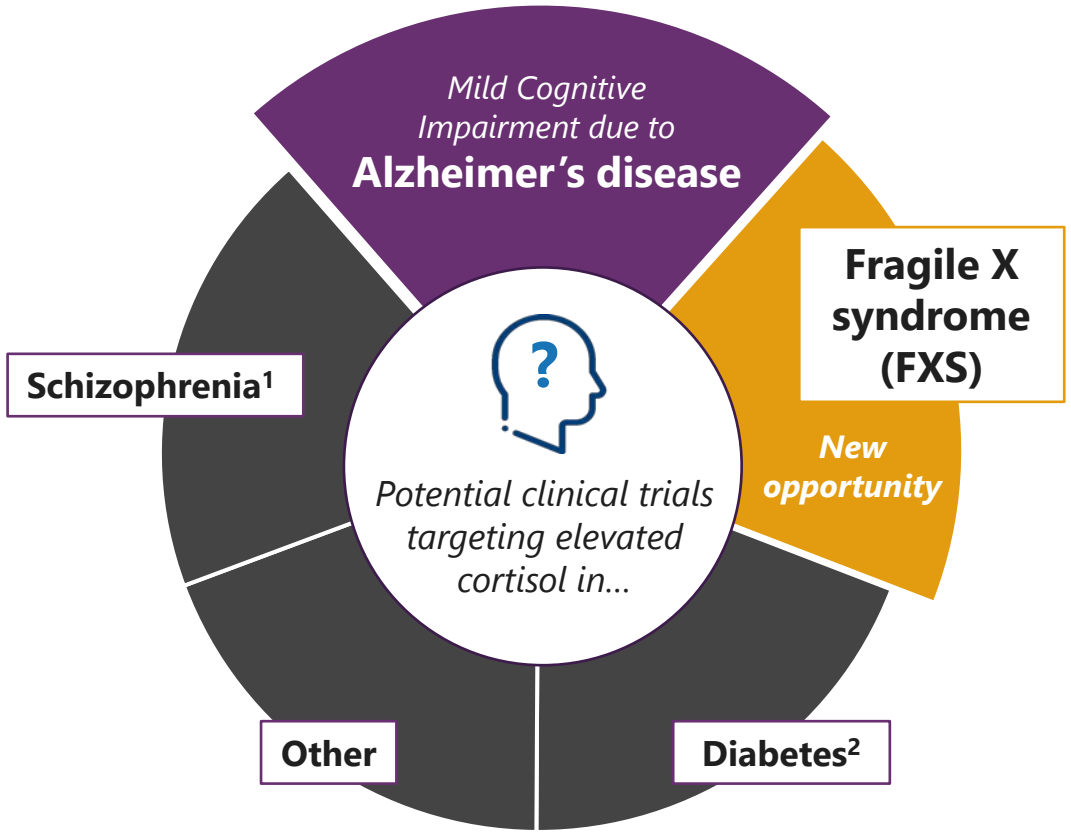
Note: Xanamem™ is a registered trademark of Actinogen Medical

1. Timing is dependent on a number of external factors (including COVID-19 restrictions and regulatory approvals)

Leveraging development across multiple indications

Xanamem's strategic development across multiple target indications, with Fragile X syndrome selected as a new strategic clinical development opportunity



FXS selected as the next clinical development opportunity for Xanamem

Core symptoms of behavioural problems, anxiety, and sleep issues associated with Fragile X syndrome selected as Actinogen's next clinical development opportunity

Follows significant clinical interest and an extensive scientific, clinical and commercial review

Potential for Orphan Drug Designation and Rare Paediatric Disease Designation provides attractive regulatory, development, and commercial benefits

XanaFX: Fully funded Phase II trial

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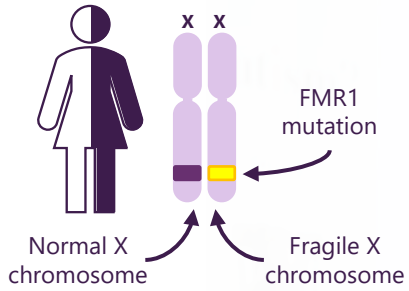
1. Cognitive impairment associated with Schizophrenia (CIAS)
2. Cognitive impairment associated with Type 2 Diabetes (CIAD)

Fragile X syndrome can be a debilitating condition

Fragile X syndrome is a rare genetic condition associated with severe symptoms (including intense anxiety) and cognitive deficit representing a significant unmet medical need with limited treatment options

FXS is caused by mutations in the Fragile X gene (FMR1) of the X chromosome.

It is the most common cause of genetically inherited intellectual disability.



Diagnosis typically occurs around 3-5 years of age.

FXS is characterised by a range of developmental problems including learning disabilities, behavioural issues including autism features, cognitive impairment, speech and language deficits, sleep issues, anxiety, and severe difficulties with regulating stress and emotions.

There are no approved drugs to treat Fragile X syndrome

Management of FXS is often complex, with life-long treatment required for patients.

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Behavioural problems, anxiety, and sleep issues in FXS

The management of FXS is often complex with limited treatment options that may cause anxiety and behavioural problems, representing a significant unmet medical need

Limited treatment options available

- Current treatments are **focused on minimising symptoms**
- Typically, therapy is combined with medications that are **not approved for use in FXS**
- There are currently **no medications targeting the anxiety and behavioural problems** associated with raised cortisol in FXS

Debilitating characteristics

Intellectual disability

Affecting quantitative skills, verbal reasoning, visual abilities, and short-term memory

Behavioural anomalies

Range from mild (e.g. social withdrawal) to severe (e.g. anxiety autism, aggression)

Impact of anxiety, sleep, and behavioural problems in FXS

Debilitating behavioural problems can **include aggression and sensory defensiveness**, which can lead to further social issues

~90% of patients suffer from symptoms of **anxiety**, representing a **significant unmet medical need**

Anxiety, sleep, and behavioural problems selected as key opportunities for Xanamem

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Source: Fisch et al. 1996; Van Esch 2019

1. Current standard of care includes speech and language therapy, special education support, occupational therapy, behaviour therapy and depending on symptoms, can also include stimulants, antidepressants, antipsychotics and anticonvulsants

Research supports Xanamem as a FXS treatment

Medical and scientific research validates cortisol as a therapeutic target in FXS

Raised cortisol associated with stress-induced behavioural problems in FXS

- Biological changes in FXS promotes elevated cortisol in the brain
- Higher salivary cortisol linked to cognitive demands and behavioral problems in FXS
- Elevated baseline cortisol associated with working memory deficits in FXS
- Increased cortisol associated with elevated symptoms of general anxiety and social avoidance in young adult males with FXS

Xanamem safely and effectively inhibits cortisol production

- ✓ Association between chronic stress and production of excess cortisol leading to changes in the brain
- ✓ Actinogen's studies demonstrate cortisol inhibition and cognitive enhancement with Xanamem in clinical trials
- ✓ Further, recent clinical results confirm that Xanamem works as designed, to penetrate the brain in concentrations that adequately inhibit the activity of the 11ß-HSD1 enzyme

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Source: Wisbeck et al. 2000; Hessl et al. 2002; Scherr et al. 2016; Matherly et al. 2018; Lupien et al. 1998, Abdanipour et al. 2015, Roberts et al. 2018

Phase II clinical trial

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

Clinical trial design

Study design	▪ Phase II proof-of-concept study ▪ Double-blind, placebo-controlled ▪ Investigator-Initiated Trial, conducted at the Murdoch Children's Research Institute and the Royal Children's Hospital, Melbourne ▪ Planning for ~40 adolescents (12-18yrs) with FXS
Primary endpoints	▪ Safety and tolerability assessment of Xanamem in this population
Secondary endpoints	▪ Efficacy assessments measuring improvement in anxiety, sleep, behavioural problems, communication, socialisation, and daily living skills

Key upcoming milestones

Planned FXS clinical trial to **commence in 1H CY21**[1]

Expected **completion within 12 months**[1]

Trial **fully funded**, with grant applications submitted to further assist with funding

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1. Timing is dependent on a number of external factors (including COVID-19 restrictions and regulatory approvals)

Partnering with Murdoch Children's Research Institute (MCRI)

MCRI team of investigators are world leaders in FXS research and have considerable expertise in paediatric clinical trials and natural history studies in Fragile X syndrome and other rare neurodevelopmental disorders

Principal Investigator

A/Professor David Godler

- Internationally recognised FXS researcher with >40 publications and 14 granted patents, primarily related to FXS
- Principal Fellow at the University of Melbourne, Department of Paediatrics and MCRI Group Leader
- Research Program Leader focused on FXS and other rare disorders, developing international infrastructure for recruitment, neuropsychological assessments, and improved FXS-specific laboratory testing and biobanking, including a registry of >250 FXS and other rare disorder patients

Supported by an experienced team of co –investigators

Prof. David Amor

- Outstanding track record with >200 publications focusing on FXS & neurodevelopmental disorders
- Lorenzo and Pamela Galli Chair in Developmental Medicine at the University of Melbourne, and senior clinical geneticist at Victorian Clinical Genetics Services and paediatrician at the Royal Children's Hospital

Prof. Noel Cranswick

- Expert in clinical pharmacology and has an international reputation for his work in medicines in children
- Extensive clinical trial experience in paediatric studies having worked on over 200 drug clinical trials

Prof. Katrina Williams

- Developmental paediatrician, public health physician, clinical epidemiologist and autism specialist
- Prof. of Paediatrics and Head of Department of Paediatrics at Monash University and a Neurodevelopmental Paediatrician at Monash Children's Hospital

A/Prof. Mathew Hunter

- Head of the Department of General Genetics, Monash Health
- Specialised in paediatrics and clinical genetics

Dr. Emma Baker

- Post-doctoral research officer and an autism and sleep specialist
- Extensive experience working with participants affected with various rare genetic disorders

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Strategic advantages

Attractive regulatory, development, and commercial benefits through potential increased speed to market, reduced costs, and enhanced competitive protection

Benefits provided by Orphan Drug and Rare Paediatric Disease Designation[1,2,3]

Development benefits	*Clinical trials for rare diseases typically enrol fewer patients, potentially decreasing costs and shortening development timelines*
Regulatory exclusivity	*Regulatory exclusivity / competitive protection, with an extended period of exclusivity in the majority of key markets including USA, Europe and Japan*
Increased speed to market	*Priority review[2], with potential to receive a second, transferable, Priority Review Voucher (PRV) from the FDA (applicable to other indications)*
Commercial incentives	*Direct commercial incentives, including tax credits, potential sale of second PRV[3]*
Dataset generated	*Data generated for FXS could be leveraged for other indications, potentially decreasing the time to market; also presents a significant potential upside with FXS-related conditions (ie. Autism Spectrum Disorder)*

1. FXS is an orphan disease, defined by its rarity, which means that there is potential for novel therapeutics targeting FXS to be granted Orphan Drug Designation; leading to regulatory, development and commercial incentives for drug developers.
2. In the USA, developers of orphan drugs for paediatric indications that have been granted a Rare Paediatric Disease Designation may apply for a Rare Paediatric Disease priority review voucher (PRV) from the FDA
3. Pending reapproval by US Congress of the Rare Paediatric Disease program

Valuable market opportunity

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

Target population	Prevalence
Behavioural problems, anxiety, and sleep in FXS adolescents	*Approx. 1 in 2500-4000 males and 1 in 7000-8000 females (averages to 1/4500)*

Substantial market opportunity[1]

~US$250m

With 14.4% compound annual growth

1. FSX market in 2026. GlobalData analyst report 2018. Projection for 7 major markets: US, France, Germany, Italy, Spain, UK, Japan

Opportunity for significant commercial transactions in FXS

Significant potential commercial opportunities available through FXS, with recent comparable partnership deals in this indication demonstrating significant commercial interest

Key commercial opportunities:

Sale of second Priority Review Voucher[1]

*Can be sold for **substantial commercial value - average disclosed selling price of ~US$133m***

Partnershsip / Takeover / License

Commercial interest demonstrated by precedent deals

Year	Target	Investor	Asset *(Phase)*	**Total** *(US$m)*
2020*	tetra THERAPEUTICS	SHIONOGI	BPN-14770 *(II)*	500
2020	tetra THERAPEUTICS	SHIONOGI	BPN-14770 *(II)*	*Equity deal to increase holding to 50%*
2018	tetra THERAPEUTICS	SHIONOGI	BPN-14770 *(II)*	160
2018	neuren pharmaceuticals	ACADIA Pharmaceuticals	Trofinetide *(II)*	465
2017	autifony THERAPEUTICS	Boehringer Ingelheim	AUT00206 *(I)*	684

**Most recent Tetra/Shionogi deal was an acquisition*

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Source: Medtrack; Businesswire

1. Potential to receive a second Priority Review Voucher upon approval in FXS – (Source: PRV value Adapted from FDA website, Company press releases, http://priorityreviewvoucher.org)

Outlook: Multiple near-term catalysts

XanaFX - Actinogen expects to complete this fully funded clinical trial within 12 months of commencement

Key catalysts:

- ❑ Finalise clinical development plan with **XanaFX protocol complete, trial sites selected**
- ❑ **Receive regulatory approval and commence next phase of clinical trials**, with XanaFX phase II proof-of-concept clinical trial expected to enrol **first patient in 1H CY21**
- ❑ Potential for **Orphan Drug and Rare Paediatric Disease Designations**, with expected regulatory, development and commercial advantages, including increased speed to market
- ❑ **XanaFX study expected to complete within 12 months** after first patient enrolled

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Note: Timing is dependent on a number of external factors (including COVID-19 restrictions and regulatory approvals)

Investment summary: Actinogen

Actinogen is developing novel therapies for cognitive impairment and neuropsychological symptoms due to raised cortisol in chronic neurological, psychiatric, developmental, and metabolic diseases, with a primary focus on Mild Cognitive Impairment (MCI) due to Alzheimer's disease

- ✓ Xanamem – a **differentiated compound** (oral, brain penetrant, selective and effective 11β-HSD1 inhibitor) with a **validated novel mechanism of action** and **strong safety profile**
- ✓ XanaHES trial **achieved robust cognitive efficacy signal with Xanamem 20mg daily.** Results endorse the cortisol hypothesis and build on the positive pharmacokinetic, pharmacodynamic, and safety data from XanADu
- ✓ Next phase of Alzheimer's disease clinical development to **target patients with MCI due to AD** – based on positive results from the recently completed XanaHES trial
- ✓ Leverage Xanamem mechanism of action across **multiple indications**, including **FXS, cognitive impairment associated with schizophrenia and diabetes**
- ✓ **Study parameters defined, including dose,** following latest trial results
- ✓ Exploring potential **partnership and collaboration funding** opportunities
- ✓ Xanamem development targeting **huge unmet medical needs** with **unsustainable healthcare costs**

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