

Investor Presentation

A novel approach to treating cognitive impairment and Alzheimer's disease

Dr. Bill Ketelbey: CEO & MD

November 2018



Actinogen
Medical

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Executive summary

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What is Xanamem

Development pipeline



Key investment highlights

Actinogen is developing innovative treatments for cognitive impairment associated with neurodegenerative and metabolic diseases with an initial focus on Alzheimer's disease



Novel compound

Differentiated with a novel mechanism of action
First-in-class, brain penetrant, orally active, small molecule, inhibitor of 11 β HSD1 enzyme
Xanamem mechanism of action validated by independent research on the cortisol hypothesis



Targeted strategic market focus

Initially focused on developing a treatment for Alzheimer's disease
Addressable market worth >US\$7.5bn with unmet needs and potential upside
Target indication underpinned by efficacy results from animal model studies



Clinical stage asset

Advanced clinical stage program assessing Xanamem in Alzheimer's disease
XanADu clinical trial fully enrolled, with results expected Q2 CY2019
Positive safety interim analysis reported in XanADu



Potential value upside

Well positioned to unlock further value
Multiple potential indications
Significant Big Pharma interest



De-risked opportunity

Fully funded programs
Additional Xanamem-related studies initiated
Additional pipeline opportunities under evaluation



Experienced leadership

Board and Management with significant drug development and investment experience, supported by key opinion leaders and Xanamem discovery team

Xanamem

Actinogen's lead compound, Xanamem, is a novel drug designed to inhibit the production of cortisol in the brain with the potential to treat cognitive impairment and Alzheimer's disease



Well researched

In clinical stage development, with over 15 years of R&D completed, and A\$40m invested to date



Well tolerated

Dosed >150 patients with acceptable clinical safety, toxicity and PK / PD¹ profile



Differentiated mechanism of action

Highly selective inhibitor of the 11 β HSD1 enzyme in the brain which reduces excess cortisol production



Validated

Symptomatic and disease modifying effects (in vivo) and effective demonstration of cortisol hypothesis (in humans)



Well protected

Composition of matter IP coverage $\geq$ 2031, patents granted in all major markets

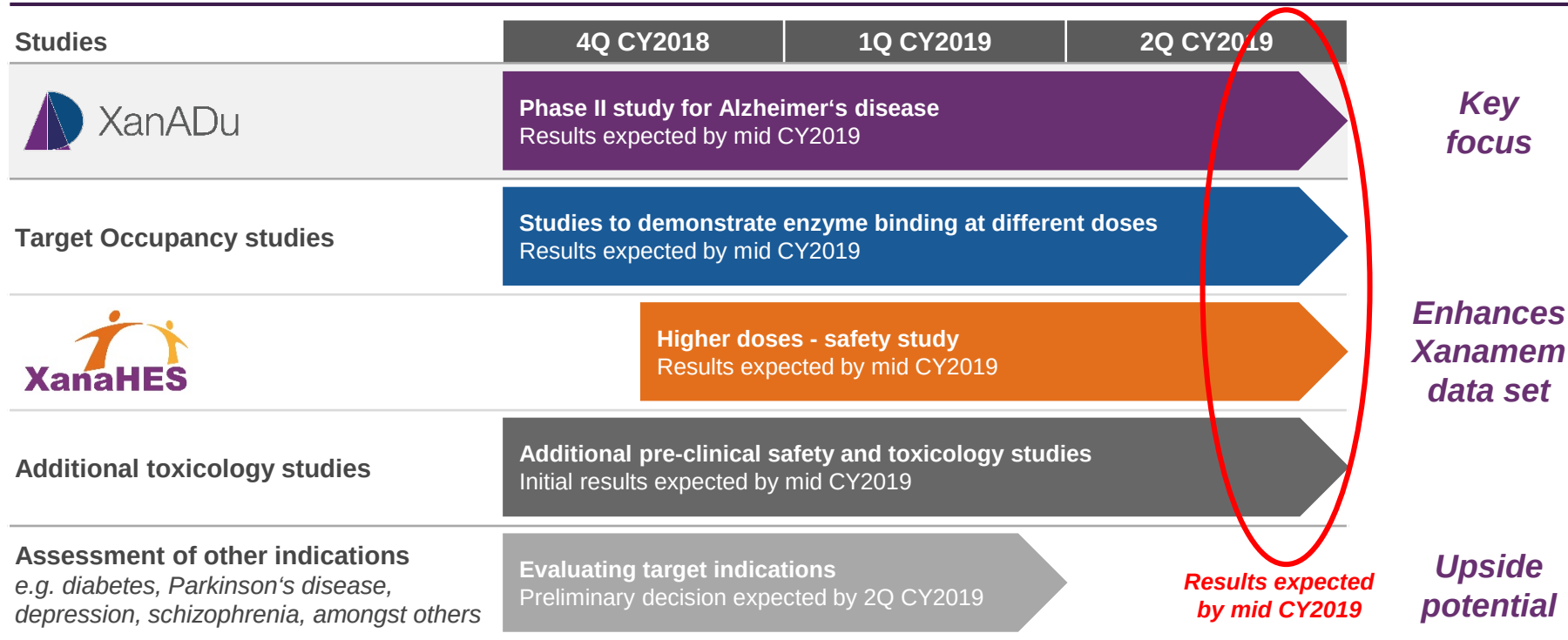


Xanamem is a novel, first-in-class, potent, orally bioavailable and brain-penetrant 11 β HSD1 inhibitor

1. PK / PD: pharmacokinetic / pharmacodynamic

Clinical development and milestones

Well progressed Phase II clinical trial (XanADu) underpinned by additional value-adding studies and an exciting Xanamem pipeline for other potential indications



Xanamem

The cortisol hypothesis

Validation of the cortisol hypothesis

Mechanism of action

Xanamem research and development

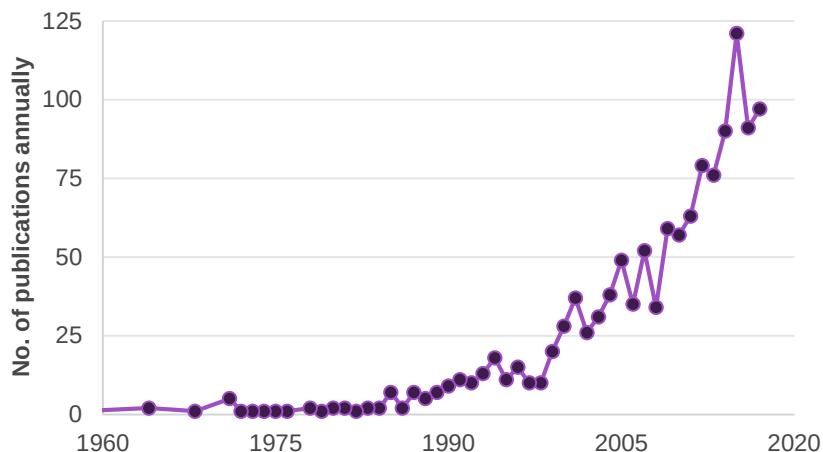
Xanamem has been developed in response to evidence that there is a strong association between chronically raised cortisol levels in the blood and in the brain, and the development and progression of Alzheimer's disease

Xanamem is underpinned by over 15 years of R&D with A\$40m invested in development

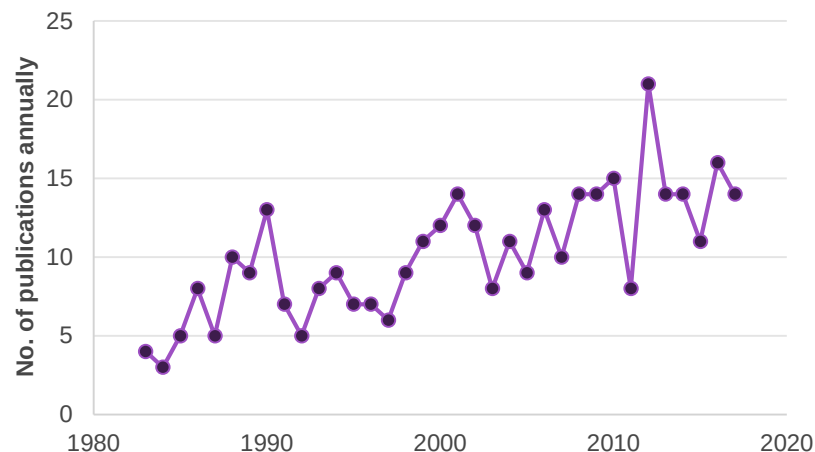
The cortisol hypothesis

A growing body of literature showing an association between cortisol and cognitive impairment

Medical publications: “Cortisol and Cognition”¹



Medical publications: “Cortisol and Alzheimer’s”¹



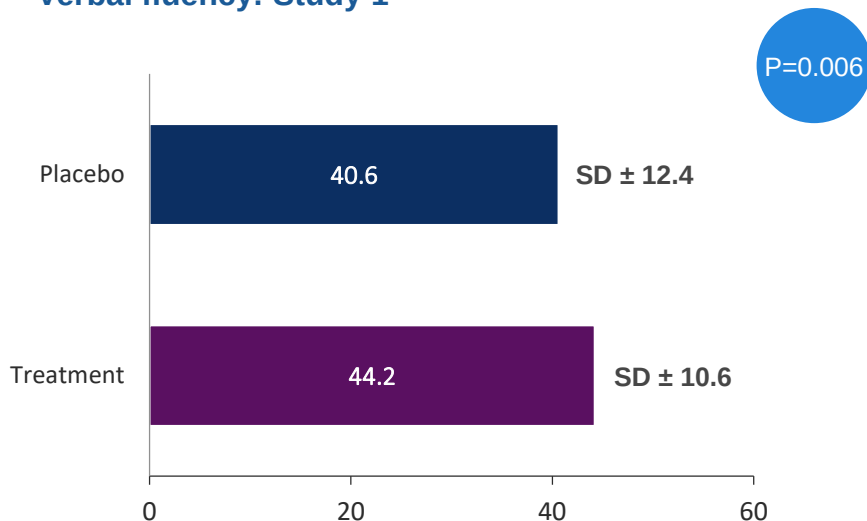
Actinogen is well positioned to leverage the growing significance of the relationship between cortisol and cognition

1. PubMed keyword search

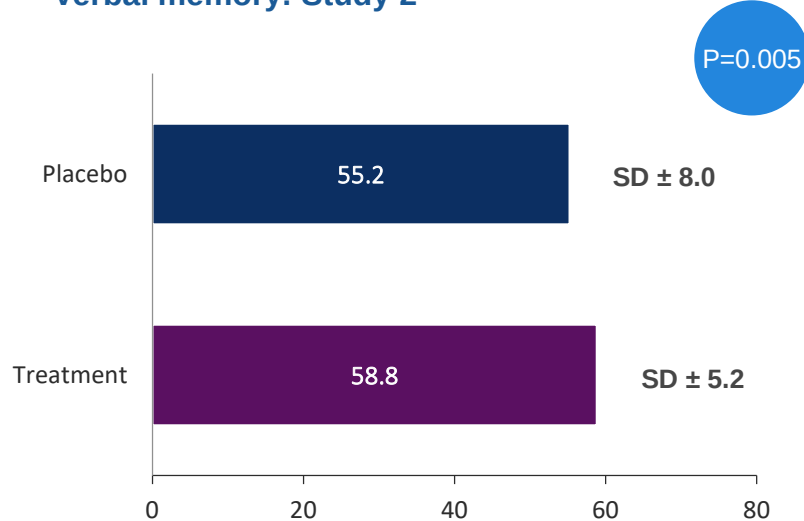
Human pilot studies validate the cortisol hypothesis

Two pilot studies indicated inhibiting cortisol production in the brain improves cognitive function in healthy elderly men and subjects with Type 2 diabetes (11 β -HSD1 inhibition with carbenoxolone – no longer commercially available)^{1,2}

Verbal fluency: Study 1¹



Verbal memory: Study 2²



Significant improvement in verbal fluency and verbal memory after only 4 and 6 weeks of treatment^{1,2}

Source: 11 β -Hydroxysteroid dehydrogenase inhibition improves cognition function in healthy elderly men and type 2 diabetics Sandeep et al., 2004 PNAS (vol. 101, no. 17) 6734-6739

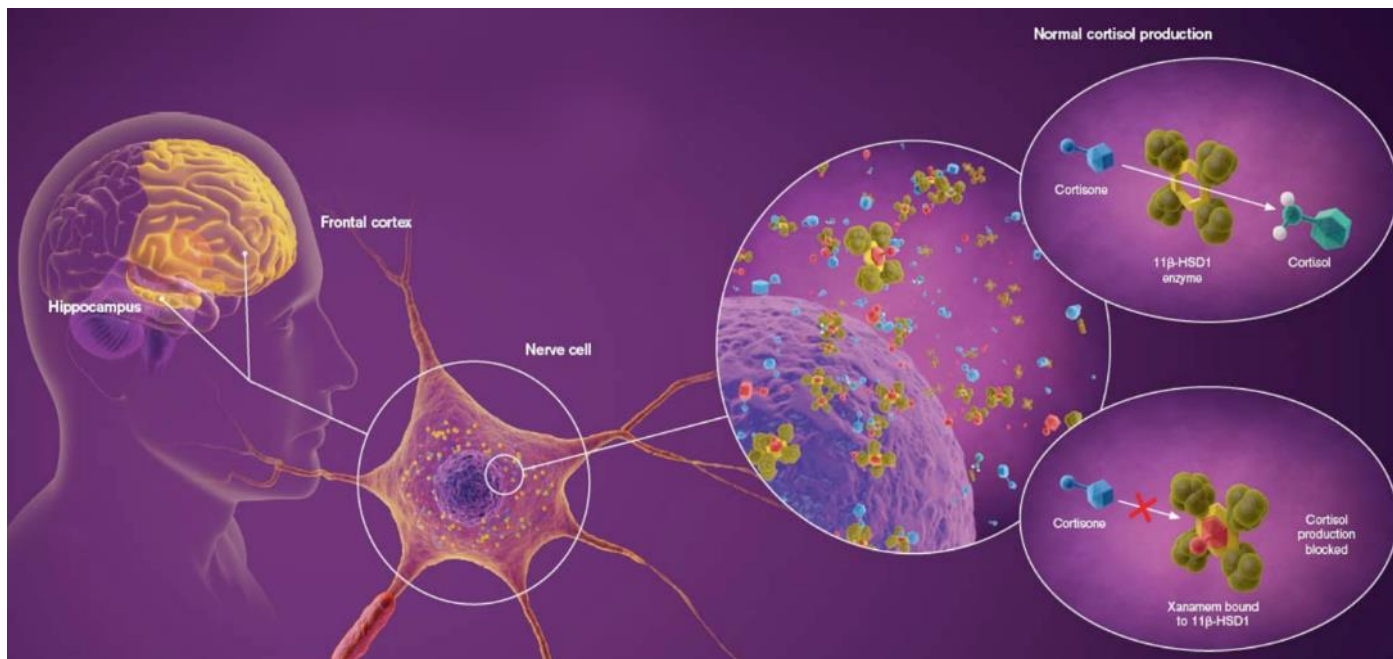
1. Study 1: 10 healthy subjects Age 55-75 (Mean Age = 65.5 ± 5.5) receiving 100mg carbenoxolone 3 times daily compared to placebo for 4 weeks, in a double-blind randomised crossover study

2. Study 2: 12 type 2 diabetics (m=9; f=3) Age 52-70 (Mean Age = 60 ± 4.9) receiving 100mg carbenoxolone 3 times daily compared to placebo for 6 weeks, in a double-blind randomised crossover study.

Mechanism of action

Xanamem inhibits the activity of the 11β HSD1 enzyme, reducing the production of cortisol in the brain

Overview

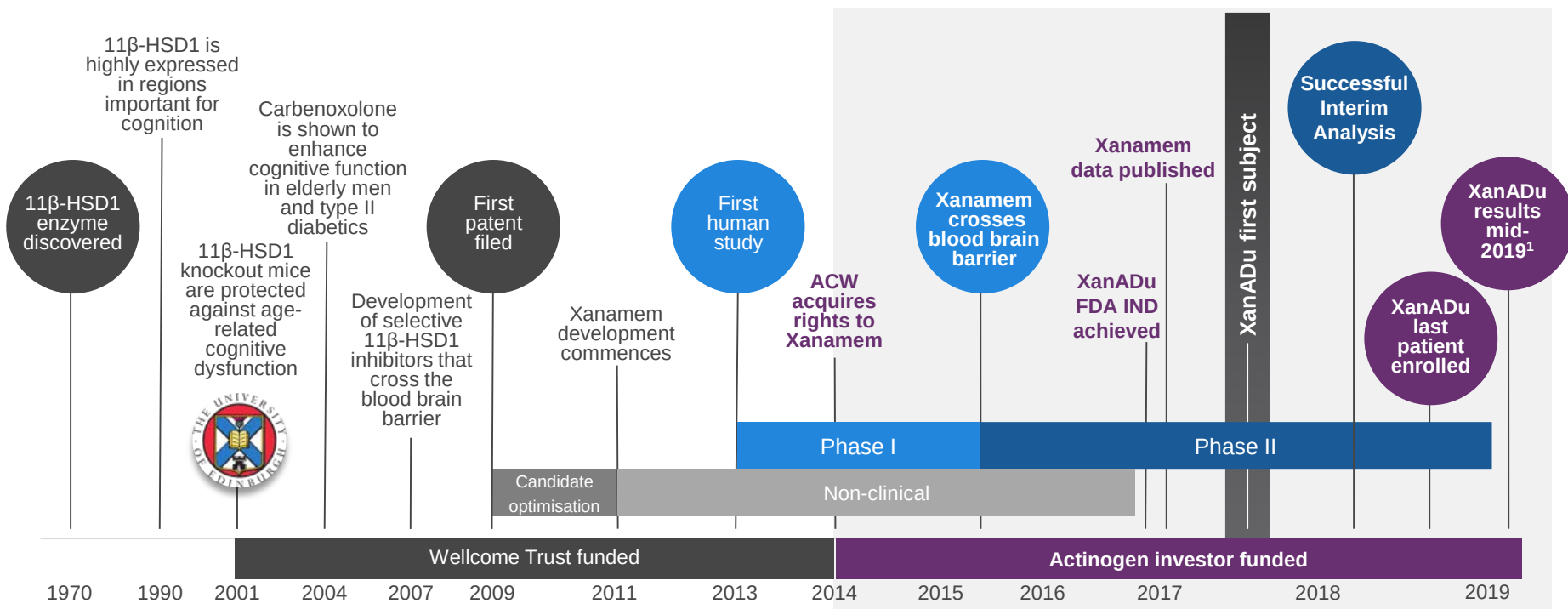


Xanamem has potential in other diseases with possible cortisol induced cognitive impairment

- **Alzheimer's disease (key focus)**
- Diabetes
- Depression
- Schizophrenia
- Parkinson's disease
- Down syndrome
- And more...

Xanamem research and development

Xanamem is underpinned by significant R&D investment and clinical progress over the last 15 years



1. Estimated timing of key milestones

XanADu

Efficacy considerations

XanADu Phase II clinical trial and milestones

Interim analysis

Favourable market dynamics

Competitive landscape

Big Pharma interest

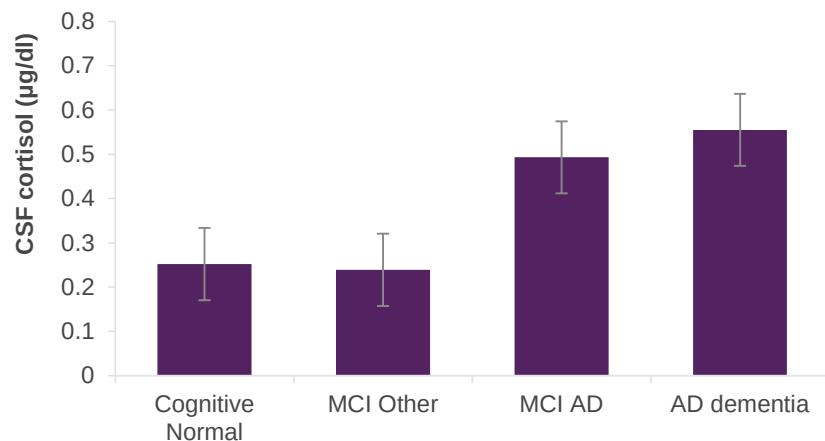
XanADu is a global Phase II double-blind, randomised, placebo-controlled study assessing the efficacy and safety of Xanamem in patients with mild Alzheimer's disease

Enrolment complete with results expected in Q2 CY2019

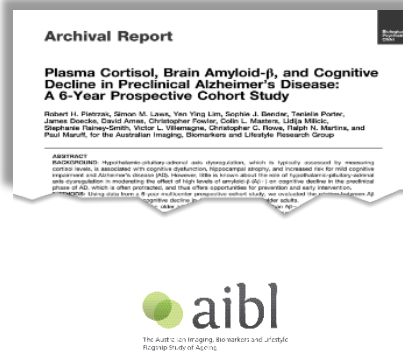
Alzheimer's strategic focus underpinned by medical research

A growing body of medical literature supports the association between cortisol and Alzheimer's disease

Raised cortisol associated with Alzheimer's disease¹



Supported by growing body of medical literature



Many studies support the association between **cortisol** and **Alzheimer's disease development and progression**²

A recent AIBL³ study provided compelling evidence that elderly subjects with **higher plasma cortisol levels** are at much greater risk of developing Alzheimer's disease

This study³ also demonstrated that **50% of those aged 65+ have raised cortisol levels**

Research suggests that lowering cortisol levels may prevent the development / progression of Alzheimer's disease

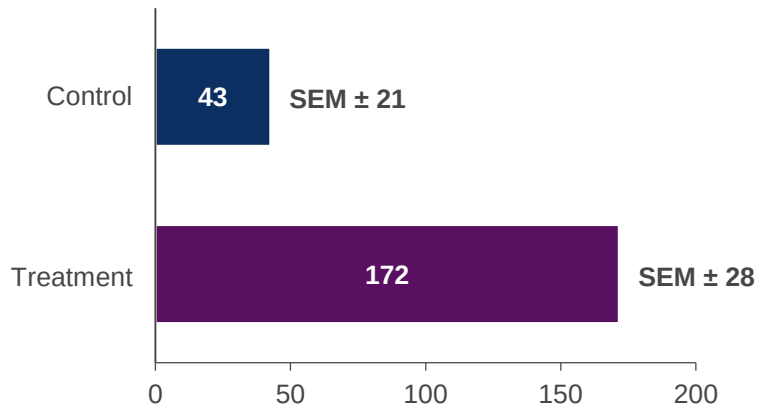
1. MCI: mild cognitive impairment; AD: Alzheimer's Disease
2. Recent studies also support the association between cortisol and cognitive impairment associated with neuroendocrine dysfunction
3. Plasma Cortisol, Brain Amyloid- β , and Cognitive Decline in Preclinical Alzheimer's Disease: a 6-Year Prospective Cohort Study. Pietrzak et al., 2017. Biological Psychiatry: Cognitive Neuroscience and Neuroimaging 2:45-52

Efficacy underpinned by animal model

Significant and rapid symptomatic and disease modifying effects demonstrated with significant improvement in cognition within one month, continuing out to 41 weeks

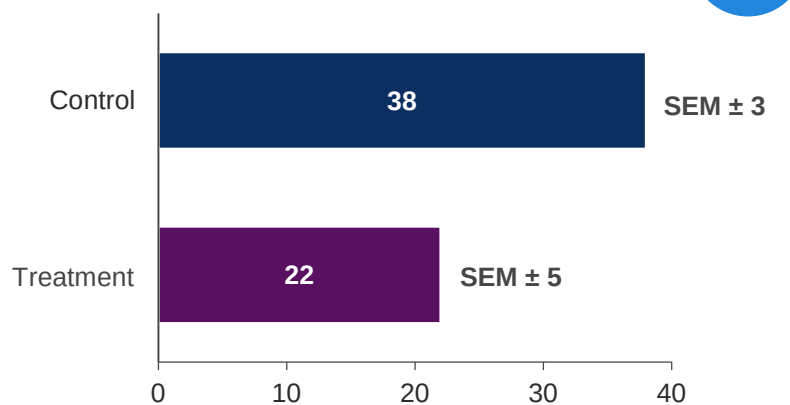
Cognition: 28 days treatment

Latency to enter dark compartment (seconds)



Amyloid clearance: 28 days treatment

Number of Plaques / brain area (total)



Results from the animal model studies underpin the significant potential of the Xanamem in Alzheimer's

XanADu Phase II clinical trial

Double-blind, randomised, placebo-controlled study to assess the efficacy and safety of Xanamem in subjects with mild Alzheimer's disease¹



Xanamem treatment course
12 weeks



186 patients with mild Alzheimer's disease (enrolment complete)²



10mg daily
Xanamem for 12 weeks (vs. placebo)



Trial conducted at 25 sites in
AUS, USA and UK

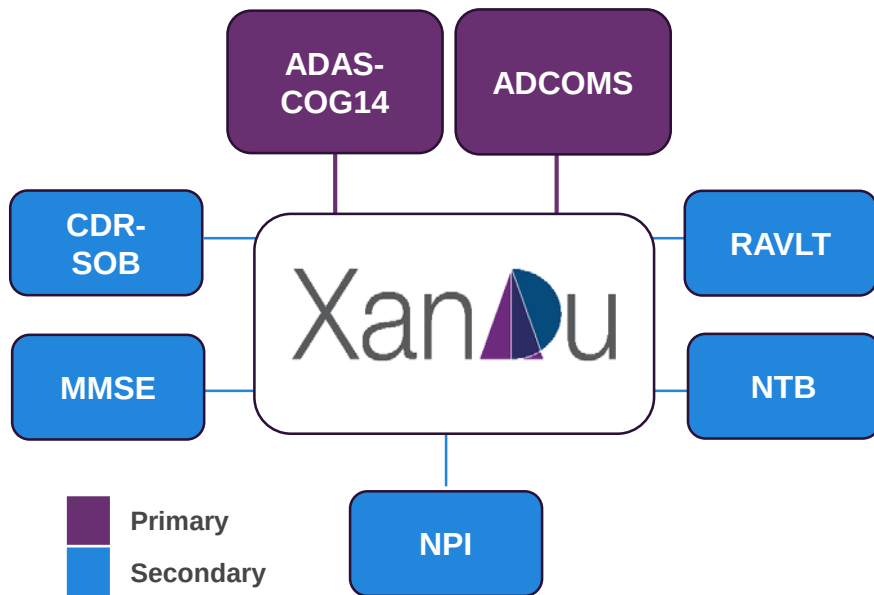
Fully funded study, fully enrolled with results due in 2Q CY2019

1. Study registered on Clinicaltrials.gov: NCT02727699
2. Fully enrolled 24 November 2018

XanADu endpoints

XanADu's primary and secondary endpoints are the standard cognitive outcome measures used in Alzheimer's disease research globally

XanADu: primary and secondary endpoints¹



Endpoints inform further development

XanADu endpoints are standard and validated assessments used in Alzheimer's disease research globally

While overlapping in many areas, each endpoint measures different discrete domains of cognition, and function in some.

XanADu is designed to identify the cognitive domains most sensitive to Xanamen's potential efficacy. Results will inform future development

1. ADAS-COG14: Alzheimer's Disease Assessment Scales – Cognitive Subscale Score (version 14); ADCOMs: AD COMposite Scores (composite data derived from ADAS-COG14, CDR-SOB and MMSE); CDR-SOB: Clinical Dementia Rating Scale – Sum of Boxes; RAVLT: Rey Auditory Verbal Learning Test; MMSE: Mini-Mental Status Examination; NTB: Neuropsychological Test Batteries; NPI: Neuropsychiatric Inventory

Interim analysis

Positive recommendations from the DSMB¹ reflect confidence in the safety of the drug and the design of the XanADu study. Supports the broader development of Xanamem



First DSMB review (23 May 2018)

- Evaluation of 50 patients' safety and efficacy data reviewed by an independent DSMB²
- **Recommendation by DSMB to continue XanADu without modification**

Second DSMB review (22 August 2018)

- Evaluation of 125 patients' safety data
- **Reaffirmed continuation of XanADu without modification**

Third DSMB review

- Expected to be completed in early CY2019

XanADu

Positive DSMB recommendations underpin the XanADu study and further development of Xanamem in other indications

1. DSMB: Data Safety Monitoring Board

2. Evaluable patients to have completed the study – note: an additional 37 patients' safety data was also included in the analysis (data was from patients still ongoing in the study)

Market dynamics of Alzheimer's disease

Presents a compelling commercial opportunity for Actinogen to target initially

Substantial target market with significant upside¹

Cortisol-high, cognition normal	Subjective memory decline	Cognitive and functional decline fulfilling dementia		
At-risk	Prodromal	Mild	Moderate	Severe
~25.0m (50% over 65 yrs)	~4.0m	~1.5m	~1.7m	~2.5m

Upside potential for earlier use Key focus

↓
>US\$7.5bn

Target annual peak sales (mild AD)²

Source: Drugs.com, Biogen, Roche, Datamonitor, Alzheimer's Association

1. Target market statistics based on the current US treatment landscape

2. Base case annual peak sales assumes: (1) Launch: US 2024, EU5, JP and ROW 2025; (2) Penetration: 30% of mild AD market in 5 years (i.e. ~470,000 in the US); (3) Pricing: US – US\$19/day (gross), ROW: 50% of US price

Underpinned by favourable market dynamics

- ✓ Targeting **large addressable** markets (US, EU5, JP)
- ✓ All **currently approved drugs are symptomatic treatments** (that do not affect disease progression) **providing limited benefit**
- ✓ Treatment **prices are robust** (despite generic competition) – with users paying for modest clinical efficacy

US branded products (gross price)



US\$10/day



US\$8/day



US\$18/day

Development pipeline of other cognitive enhancers

Xanamem is one of the most advanced cognitive enhancers currently in development¹

Company	Drug candidate	Mechanism	Phase (status)	Upcoming milestones ²	
	Xanamem	11 β HSD1 inhibitor	II (ongoing)	April 2019	Results available by mid CY2019 Estimated primary completion April 2019
	SUVN-502	5HT6 antagonist	II (ongoing*)	April 2019	Estimated primary completion *Target to complete patient recruitment by end CY2018
	Neflamapimod	p38 MAPK inhibitor	II (ongoing)	June 2019	Estimated primary completion
	Bryostatin 1	Protein Kinase C Epsilon activator	II ³ (ongoing)	July 2019	Estimated primary completion ³
	BHV4157	Na ⁺ channel blocker	II / III (ongoing)	January 2020	Estimated primary completion
	BI425809	Glycine transport inhibitor	II (ongoing)	August 2020	Estimated primary completion
	GV-971	Unknown	III**	**Phase III trial conducted in China successfully completed September 2018 / international trial is planned	
	Anavex 2-73	SIGMAR1 agonist	IIa	Initiation of Phase IIb / III announced in August 2018 – no evidence in clinical trial registries	
	HTL0018318	M1 agonist	II***	***Phase II trial placed on hold in September 2018 prior to initiation due to unexpected primate toxicology	

1. Some programs that may be relevant are not included due to lack of development (e.g. Sinphar Pharmaceuticals: STA-1; Allergan: CPC-201) or because they are more commonly referred to as disease modifying therapies (e.g. Cognition Therapeutics: CT1812; Daehwa Pharma: DHB1401; Agene Bio: AGB101)
2. Estimated primary completion based on clinicaltrials.gov information – unless additional information is available
3. Completed Phase II in May 2017 with equivocal results. New Phase II initiated in June 2018 with primary completion expected in July 2019

Comparison of Alzheimer's disease treatments

Actinogen's novel treatment for Alzheimer's disease is clearly differentiated and may be used in combination with existing cognitive enhancers and potential anti-amyloid drugs (currently in development)

Overview

	Xanomem	Cognitive enhancers	Anti-amyloid drugs
Status	In development	In market ¹	In development
Mechanism of action	Targets cortisol	AChE ² inhibitors, NMDA ² receptor antagonist	Anti-amyloid
Administration	Oral (small molecule)	Oral (small molecule)	Injectable IV / SC ³ (biologics)
Evidence of disease modification	✓ ⁴	✗	✓
Duration of effect (>8 months)	✓ ⁴	?	✓
Potential to treat 'at risk' patients	✓	✗	✓
Applicable to other cognitive disorders	✓	✗	✗
No SAEs identified	✓	✗	✗
No biomarker required	✓	✓	✗
Low cost of goods	✓	✓	✗

Xanomem may support potential combination therapy, with existing treatments and other drugs currently in development, to improve patient outcomes

- Approved cognitive enhancers have different mechanism of action and varying degrees of benefit and duration
- Despite promising data, anti-amyloid therapy has high costs, compliance challenges and requires IV / SC administration

1. Analysis excludes other cognitive enhancers currently in development
2. AChE: acetylcholinesterase; NMDA: N-methyl-D-aspartate
3. IV: intravenous; SC: subcutaneous
4. Evidence of disease modification and duration based on animal model studies

Significant headwinds for BACE inhibitor development

Significant opportunity for Xanamen development, with recent study data indicating that anti-amyloid may not be efficacious as initially expected

Overview¹

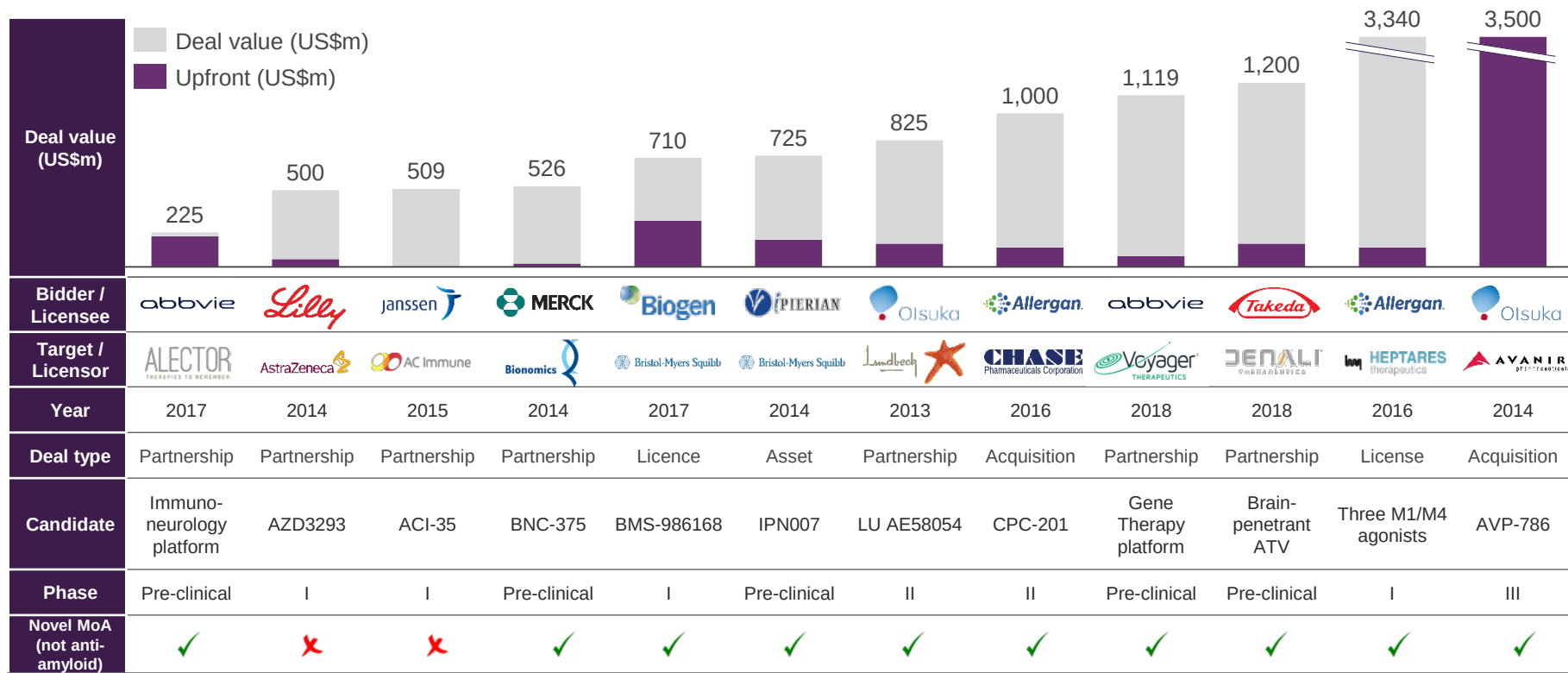
- Results indicate **potent anti-amyloid activity has not translated to substantial cognitive benefit**
- Trending / actual cognitive worsening was observed** across multiple compounds

Company	Compound (Phase) Status	Population	CSF A β lowering range	Cognition comments
 MERCK	Verubecestat (III) Stopped for futility	Mild moderate	60% - 80%	Early: Trend for cognitive worsening Overall: No difference
		Prodromal	60% - 80%	Early: Cognitive worsening Overall: Cognitive worsening
 	Lanabecestat (III) Stopped for futility	Prodromal – mild	55% - 75%	Early: Trend for cognitive worsening Overall: Data not locked
		Mild	55% - 75%	
	Atabecestat (III) Stopped for hepatic safety	Cognitively unimpaired	50% - 82%	Early: Trend for cognitive worsening - Cognitive worsening Overall: Dosing discontinued
	LY3202626 (II) Stopped for futility	Mild dementia	70% - 90%	Early: Trend for cognitive worsening - Equivocal Overall: Dosing discontinued
 	Elenbecestat (III) Ongoing	Mild moderate	~60%	Early: Trends for improvement Overall: General trends for improvement
 	CNP520 (II/III) Ongoing	Cognitively unimpaired	20% - 90%	Early: Not applicable Overall: No difference

1. Information presented at CTAD (Clinical Trials on Alzheimer's Disease) Conference held in Barcelona in October 2018

Big Pharma interest

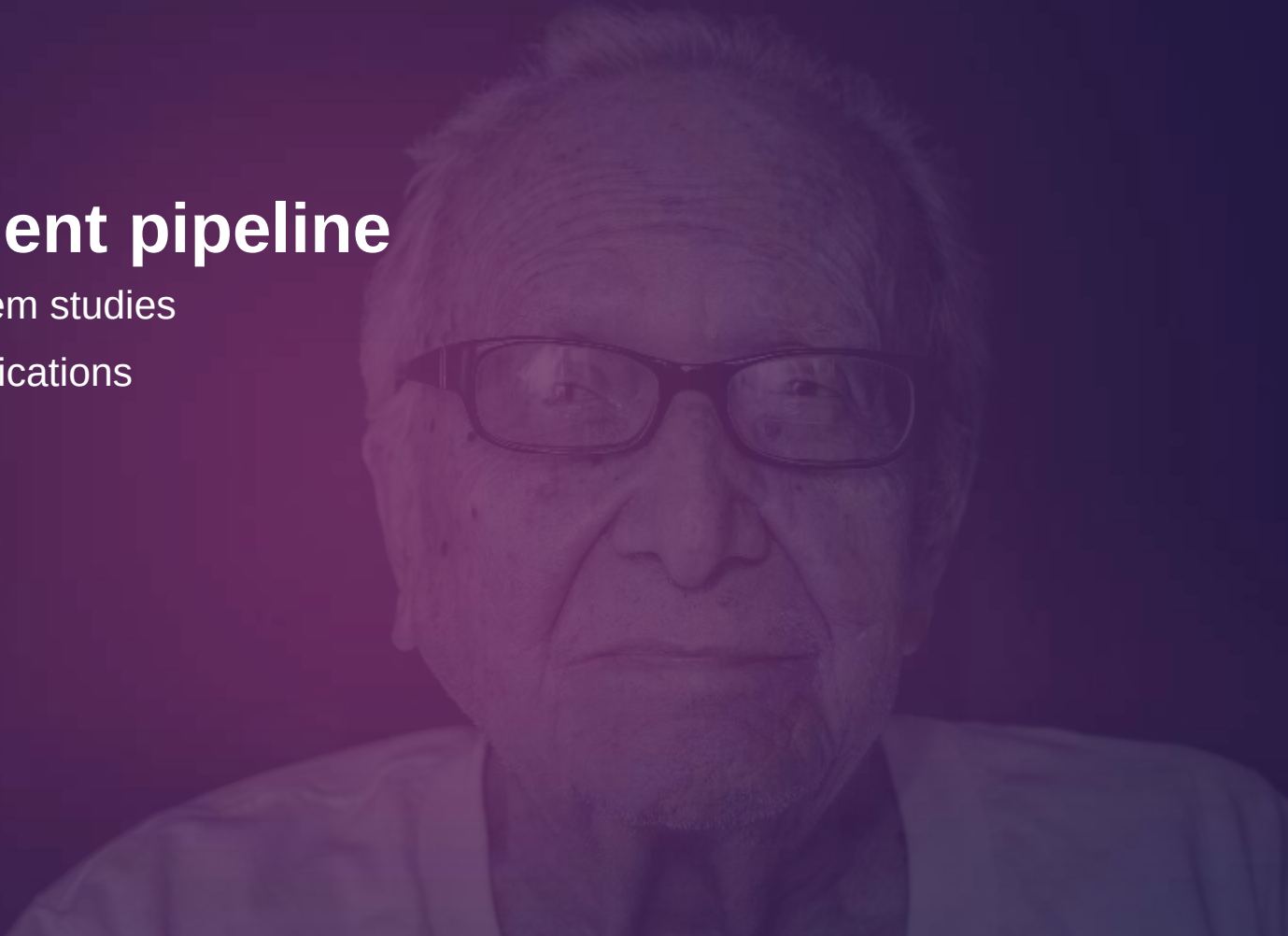
Global Big Pharma demonstrating strong M&A interest in acquiring or partnering with companies and licensing novel mechanism of action assets with Alzheimer's disease as the lead/key indication



Development pipeline

Additional Xanamem studies

Other potential indications



Additional value-adding Xanamem studies

Actinogen is focused on completing nine key additional studies to enhance the Xanamem data set, which can also be potentially leveraged into other indications



Target occupancy study

Aims to accurately demonstrate the effect different doses of Xanamem has on inhibiting the 11 β -HSD1 enzyme in the human brain and to optimise Xanamem dosing

Currently underway with
results expected in 2Q CY2019



Higher dose safety study

To expand the safety data-set for Xanamem and explore potential for higher doses of the drug to be used in Alzheimer's and other indications

XanaHES study initiated with
**initial results expected in 2Q
CY2019**



Further safety / toxicology studies

To allow for longer treatment periods, as routinely required by global regulatory authorities in the development of any drug

Additional studies initiated with
results expected in 6-12 months

Actinogen is fully funded to complete these additional Xanamem studies

Other potential indications

Actinogen is also focused on developing Xanamem in other indications to optimise shareholder value

Overview



Multiple potential target indications beyond Alzheimer's represent significant market expansion opportunities



Growing literature on cortisol-induced cognitive impairment associated with many conditions



Actinogen undertaking a detailed review to identify best additional target indications



Development program leverages existing data from earlier clinical programs

Possible target indications

Depression

Diabetes

Schizophrenia

Parkinson's disease

POCD & TBI ¹

Post-MI, PVD
Stroke & HT ²

Down syndrome

And more..

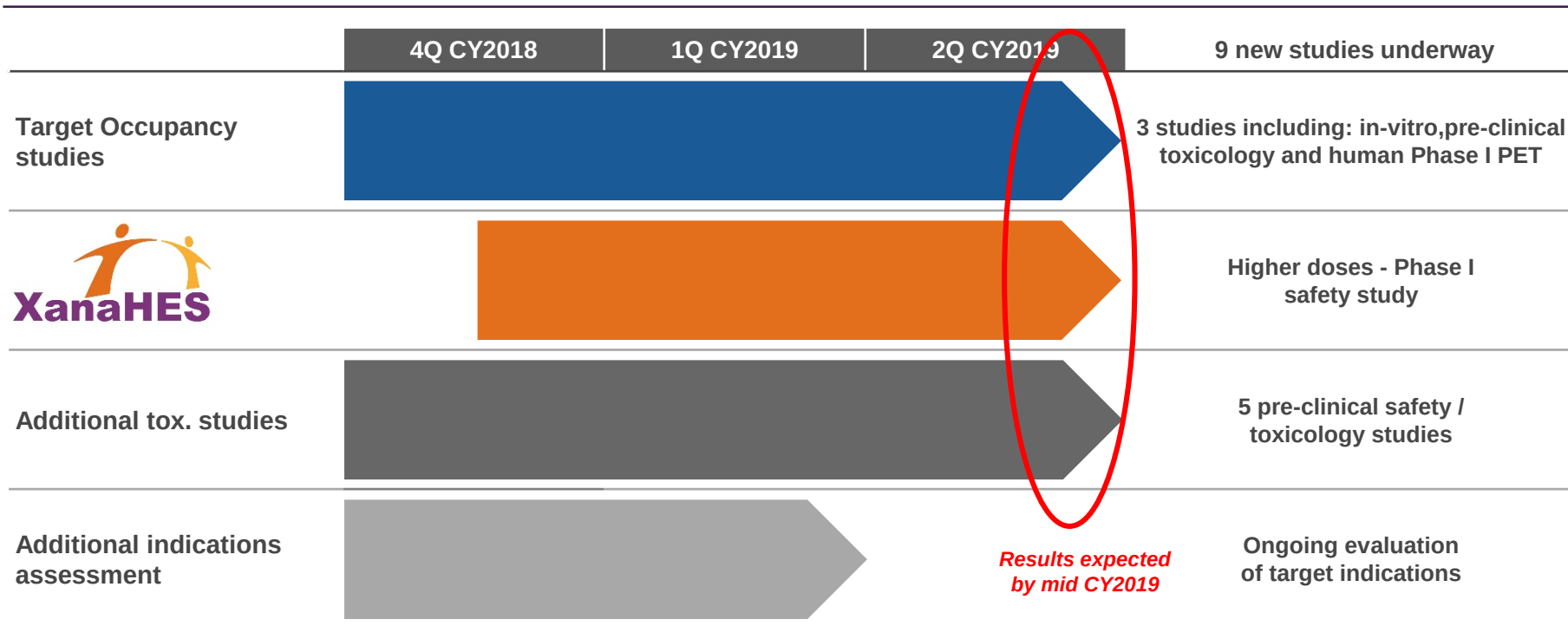
Preliminary assessment currently underway to identify high priority indications for development

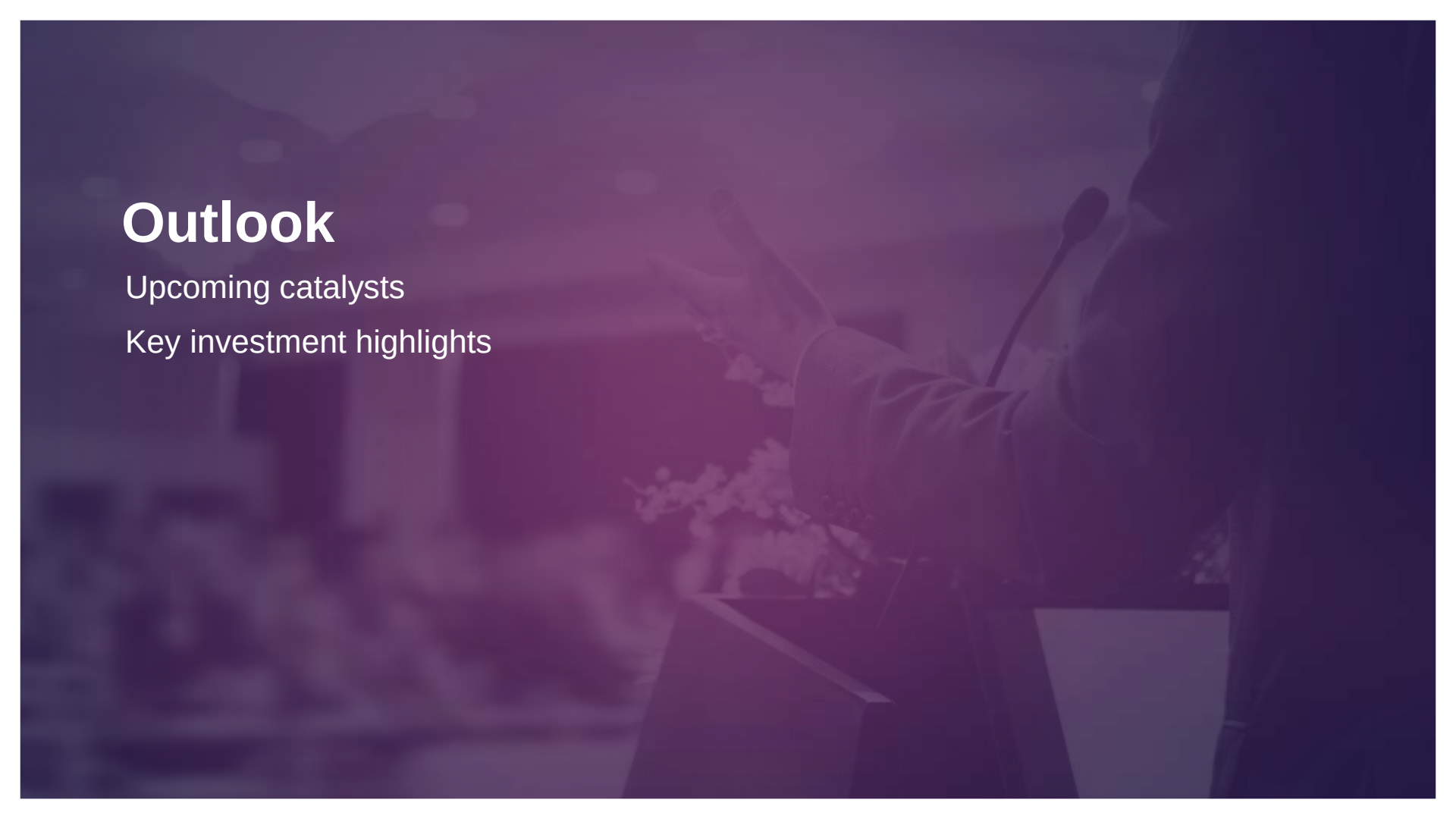
1. Post-operative cognitive decline & Traumatic brain injury

2. Post-myocardial infarction, Peripheral vascular disease & Hypertension (peripheral & intra-cranial)

Development pipeline

Multiple studies are currently underway to enhance the Xanamem data set, with results expected in 2Q CY2019, and preliminary decision on assessment of other indications planned for 1Q CY2019





Outlook

Upcoming catalysts

Key investment highlights

Upcoming catalysts

Significant upcoming milestones across first half 2019

Studies	4Q CY2018	1Q CY2019	2Q CY2019	Key catalysts
 XanADu				Results expected to be available by mid CY2019
Target occupancy studies				Results expected to be available by mid CY2019
 XanaHES				Results expected to be available by mid CY2019
Additional tox. studies				Initial results expected by mid CY2019
Additional indications assessment				Preliminary decision expected by 2Q CY2019
Strategic discussions				Ongoing discussions with potential commercial and strategic partners

Actinogen is fully funded to complete XanADu and other key studies

Proactive strategic business development

Continued strategic engagement with prospective development and commercial partners in the lead up to XanADu results

Focus on progressing collaboration and commercial discussions with prospective big pharma partners, and presenting to, and educating the scientific community

Planned H1 CY2019 Partnering and Investment Conference Attendance

JP Morgan Healthcare Conference (January, San Francisco)



SACHS Neuroscience (January, San Francisco) – Oral Presentation



BIO-Europe Spring 2019 (March, Vienna)



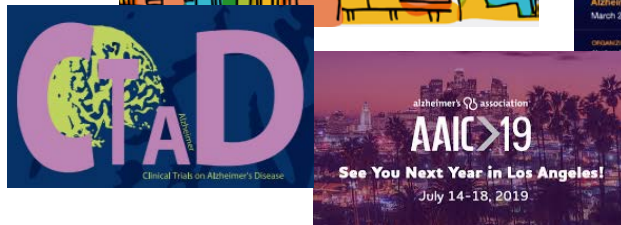
BIO 2019 (June, Philadelphia)

Planned CY2019 Scientific Conference Attendance

AD/PD 2019 (March, Lisbon)



AAIC 2019



CTAD 2019

Key investment highlights

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Additional pipeline opportunities under evaluation



Experienced leadership

Board and Management with significant drug development and investment experience, supported by key opinion leaders and Xanamem discovery team

Appendix

Corporate overview

Senior leadership

Advisory boards

IP protection



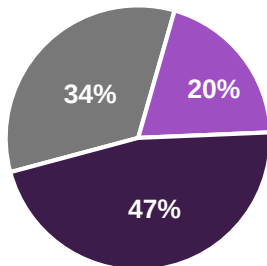
Corporate overview

Actinogen is an ASX-listed biotech company focused on innovative approaches to treating cognitive impairment associated with chronic neurodegenerative and metabolic diseases

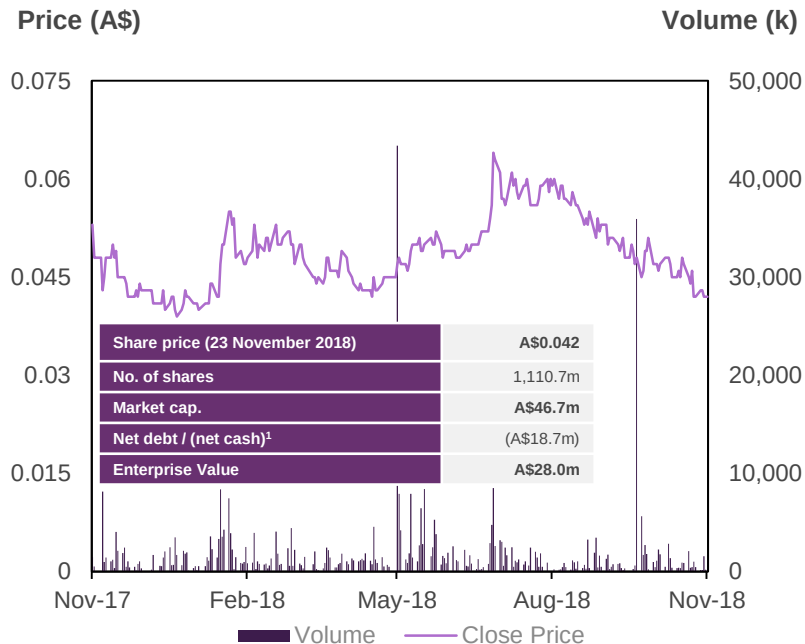
Overview

- Actinogen is developing Xanamem, a novel therapy for Alzheimer's disease with significant market potential
- Actinogen is completing a Phase II double-blind, 12 week, randomised, placebo-controlled study (XanADu) in Alzheimer's disease
- XanADu is designed to assess the safety, tolerability and efficacy of Xanamem in subjects with mild Alzheimer's disease

Key shareholding metrics



LTM share price performance and trading metrics



Note: 1: Net cash of A\$18.7m incorporates a A\$3.2m R&D rebate received in October and the Company's September quarter cash balance of A\$15.6m

Substantial Institutional investment in Actinogen*



Recognises potential and endorses strategy

Positive interim analysis catalyses significant \$15M investment through Placement

Leading investors enter register:

- USA specialist biotech investor **Biotechnology Value Fund L.P.**
- Australian institutions **Platinum Investments Management** and **Australian Ethical Investment**

Strong endorsement - Placement price represents a **13.4% premium** to the 5-day VWAP

BVF cornerstones Placement - largest shareholder with a **19.97% holding**

Funding to advance the development plan through additional Xanamem studies.



* Announced 23 May 2018

Board of Directors

Commercially experienced and globally recognised leadership team with decades of experience in drug development and biotech investment



**Dr. Geoff
Brooke**

Chairman

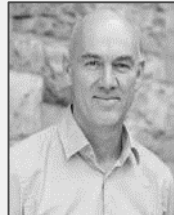
- **30+ years experience** in the healthcare investment industry
- Founder and MD of Medvest Inc and GBS Venture Partners
- MBBS (University of Melbourne); MBA (IMEDE, Switzerland)



**Dr. Bill
Ketelbey**

CEO & MD

- **30+ years experience** in the healthcare, biotech and pharmaceutical industries
- Formerly senior international roles at Pfizer; Director at the Westmead Institute of Medical Research
- MBBCH (University of the Witwatersrand); FFPM; MBA (Macquarie); GAICD



**Dr. Jason
Loveridge**

*Non-executive
director*

- **20+ years experience** in biomedical technology industry
- Venture investor with JAFCO Nomura; Non-Executive Director of Resonance Health (ASX: RHT); CEO of 4SC AG
- B.Sc (UNSW), PhD (University of Adelaide) FRSM



**Dr. George
Morstyn**

*Non-executive
director*

- **25+ years experience** in biotechnology investment
- Board member of Cancer Therapeutics, Symbio and Biomedvic; Former Senior VP and SMO at Amgen
- MBBS (Monash University); PhD (Walter and Eliza Hall Institute); FRACP; MAICD



Advisory Boards

World's premier academics involved in the development of Xanamem and as a novel treatment for Alzheimer's disease

Xanamem™ Clinical Advisory Board

*Positions Xanamem at the forefront of
Alzheimer's drug development*



**Prof. Craig
Ritchie** *Chair*



THE UNIVERSITY
of EDINBURGH



**Prof. Colin
Masters** *AO*



The Royal
Melbourne Hospital

THE
FLOREY

INSTITUTE OF NEUROSCIENCE & MENTAL HEALTH



**Prof. Jeffrey
Cummings**



**Cleveland
Clinic**



**Prof. Jonathan
Seckl**



THE UNIVERSITY
of EDINBURGH



**Prof. Brian
Walker**



**Newcastle
University**



**Prof. Scott
Webster**



THE UNIVERSITY
of EDINBURGH

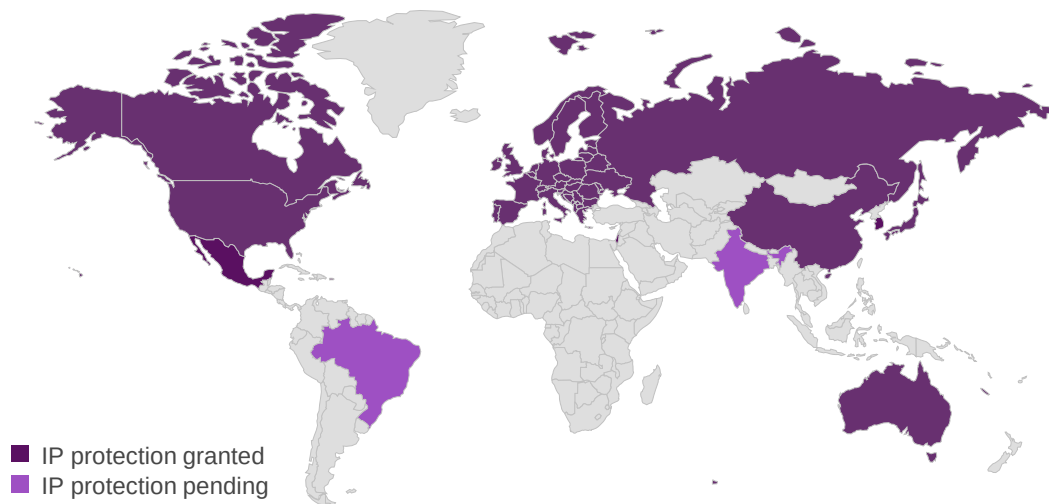
Scientific Advisory Board

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

IP protection

Actinogen maintains a broad granted composition of matter patent estate, extending to at least 2031, with key patents granted in all major target markets

Geographic patent overview



- Actinogen's patent portfolio **covers a broad range of neurological and metabolic diseases** including Alzheimer's disease
- Xanomem **patents granted in key markets** that account for over 90% of the global Alzheimer's market
- Actinogen's patent portfolio **extends to at least 2031**

>90% of the global Alzheimer's disease market

Disclaimer

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