

Australia Biotech Invest & Partnering 2018

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

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Actinogen
Medical

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 is 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

Fully funded advanced clinical stage program
Alzheimer's trial recruitment complete - top line results expected by mid CY2019
Reported positive interim analysis



Potential value upside

Well positioned to unlock further value
Significant Big Pharma interest



De-risked opportunity

Additional Xanamem – related studies initiated
Additional pipeline development opportunities



Experienced leadership

Significant drug development and investment experience
Leading clinicians and Xanamem discovery team

What is 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 prevents 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

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



174 patients with mild Alzheimer's disease (**recruitment complete**)²



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



Trial conducted at 25 sites in
AUS, USA and UK

Fully funded study on track to complete enrolment in 4Q CY2018 with top line results in 2Q CY2019

1. Study registered on Clinicaltrials.gov: NCT02727699
2. As at 26 October 2018

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 sales²

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



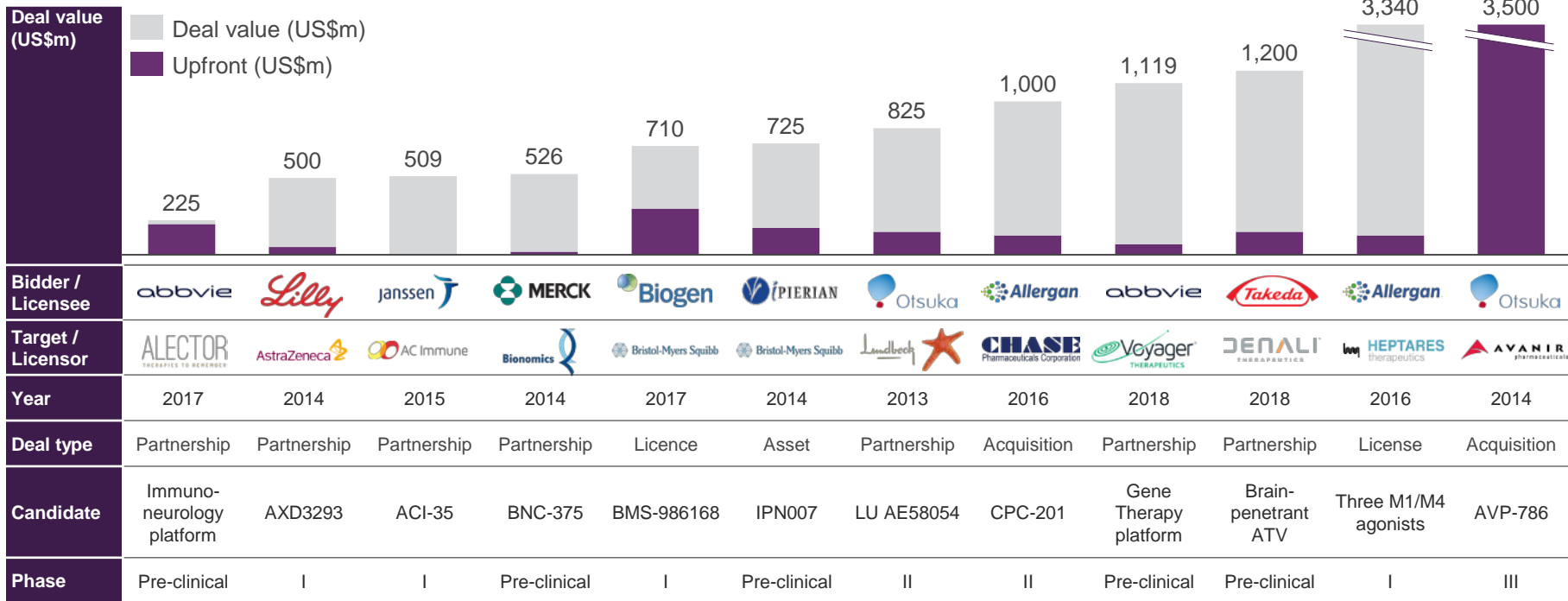
US\$8/day



US\$18/day

Big Pharma interest

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



Additional Xanamem studies

Actinogen is focused on completing key additional studies to enhance the Xanamem data set



Target occupancy study

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

Currently underway with **results expected in 2Q CY2019**



Higher dose safety study

To expand the safety data-set for Xanamem and allow for higher doses of the drug to be used (including in non-Alzheimer's applications)

Study is expected to **initiate in 4Q CY2018**



Further safety / toxicology studies

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

Studies are expected to **initiate in 4Q CY2018**

Actinogen is fully funded to complete these key Xanamem studies

Other potential indications

Secondary focus is on developing the use of 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 intends to follow a rapid development pathway to identify suitable target indications



Development program leverages existing data from earlier clinical programs

Possible target indications

Diabetes

Depression

Parkinson's disease

Schizophrenia

Post-traumatic
stress disorder

And more..

Preliminary assessment currently underway to identify high priority indications for development

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



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Prof. Colin Masters
AO



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Prof. Scott Webster



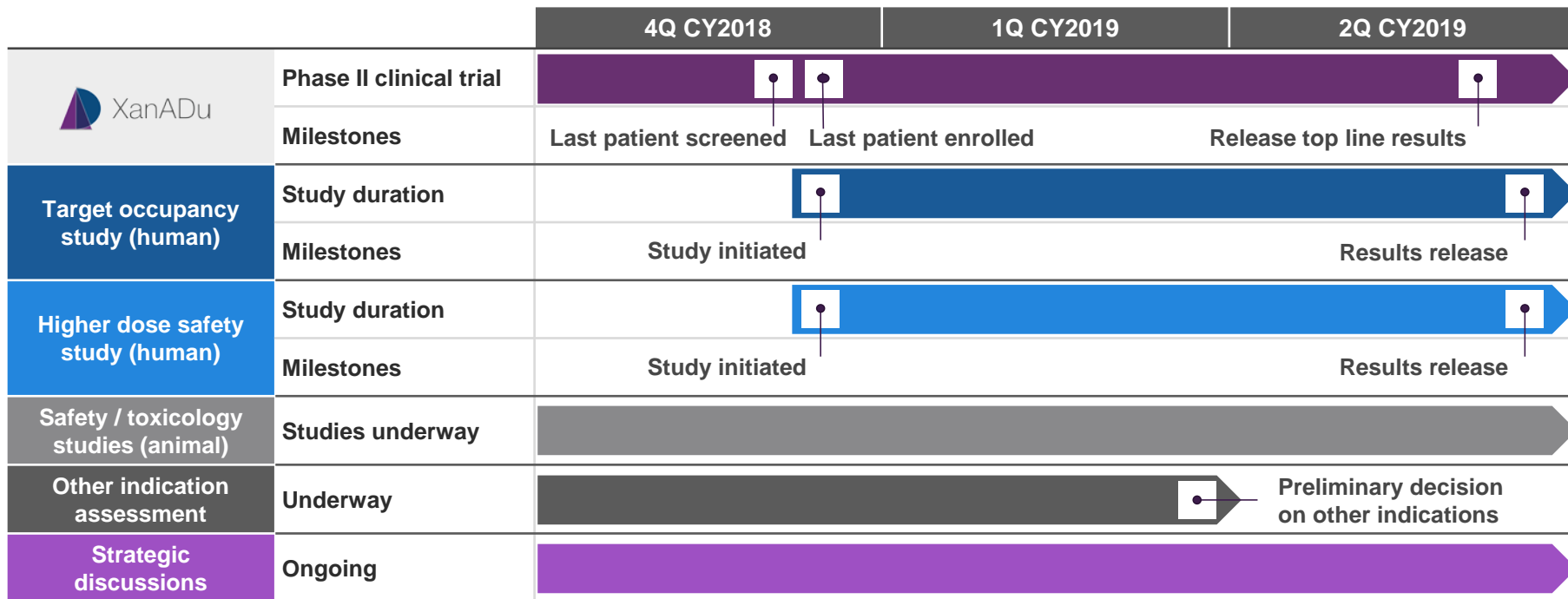
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Scientific Advisory Board

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

Upcoming catalysts

Significant upcoming milestones across 2018/19



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