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Year 18 (May '18 - May '19)	-2.3%
Year 19 (May '19 - Current)	58.4%
Cumulative Gain	1137%
Av. Annual gain (19 yrs)	18.3%

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# Bioshares

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*Delivering independent investment research to investors on Australian  
biotech, pharma and healthcare companies*

Extract from *Bioshares* –

## **Actinogen Gets Early Positive Data in Healthy Older Adults with Higher Dose of Xanamem**

In May this year, Actinogen Medical (ACW: \$0.046) reported that its Phase II trial in 186 subjects with mild dementia due to Alzheimer's disease failed to show any benefit in the 12 week study, which explored a daily oral dose of the company's drug candidate, Xanamem, of 10mg.

Last week Actinogen reported some positive cognitive and functional data in a 12 week study in older *healthy* volunteers, this time exploring twice the dose, of 20mg a day of Xanamem. Previous clinical studies had shown that target engagement occurred at 20mg a day, which supports the view that the Phase II study completed earlier this year explored an insufficient dose level.

Using a specially designed battery of cognitive and functional tests from Cogstate, the trial showed a statistically significant improvement in working memory ( $p<0.01$ ) and visual attention ( $p=0.05$ ), and a medium treatment effect in psychomotor function ( $p=0.09$ , not statistically significant). Effects on longer-term memory – Paired Associate Learning, Memory and Visual Learning – were minor. Assessment of executive function was not conducted in this trial.

### **Analysis**

These results for Xanamem in healthy volunteers showed a consistent effect on attention, including working memory. The implication here is that the drug candidate may have an application for the treatment of attention disorders, including mood disorders such as bipolar and schizophrenia.

Poor working function is also a major issue in patients with Alzheimer's disease according to CEO Bill Ketelbey.

A meaningful effect on longer term memory and learning capabilities was not shown in this test, however, it may be more difficult to show effect in some of these capabilities where there are no serious gaps or deficiencies in healthy subjects.

Another positive outcome from the study is that the results were durable, with a sustained effect over the 12 week period. And that this effect was measured in healthy, albeit older, volunteers, is also promising, given the challenge in assessing benefits in a largely healthy population (of 42 subjects).

A statistically significant ( $p<0.001$ ) reduction was achieved in cortisol levels in the plasma, which is consistent with the drug's intended mechanism of action. Actinogen has shown that between 50%-85% target occupancy of the enzyme is achieved in the brain.

Across all six cognitive measures, the results were positive as measured by the 'Cohen's

*Continued over*

d' treatment effect. The treatment effect observed in this trial for the six measures were 0.83, 0.76, 0.67, 0.48, 0.19 and 0.08. These figures can be compared to the Alzheimer's drugs– the cholinesterase inhibitors, including Aricept – which had a treatment effect on between 0.15 - 0.28 on ADAS-Cog with low, medium and high doses.

Ketelbey said during a conference call last week that all of the data being generated with Xanamem will help shape the direction and strategy for this asset. Additional clinical studies are expected to commence next year according to Ketelbey who does not believe that a higher dose needs to be examined at this point.

### Summary

Actinogen has now shown that its Xanamem drug candidate does cross the blood-brain-barrier, that it inhibits the target enzyme and that it reduces blood cortisol levels. At the 20mg a day dose, it has shown to be safe with no serious adverse events, and it has shown to exert an effect on cognition, at this stage more with working memory and attention than on longer term memory.

Once all of the current studies are completed, the company will decide on the next stages over development with this compound. Current data would suggest that the next stage of investigation of this drug candidate is warranted.

Actinogen is capitalised at \$51 million. It held cash of \$7.7 million at the end of June with a \$4.6 million R&D tax rebate also expected.

*Bioshares* recommendation: **Speculative Hold Class B**

**Bioshares**

**How Bioshares Rates Stocks**

For the purpose of valuation, Bioshares divides biotech stocks into two categories. The first group are stocks with existing positive cash flows or close to producing positive cash flows. The second group are stocks without near term positive cash flows, history of losses, or at early stages of commercialisation. In this second group, which are essentially speculative propositions, Bioshares grades them according to relative risk within that group, to better reflect the very large spread of risk within those stocks. For both groups, the rating “Take Some Profits” means that investors may re-weight their holding by selling between 25%-75% of a stock.

**Group A**

Stocks with existing positive cash flows or close to producing positive cash flows.

- Buy** CMP is 20% < Fair Value
  - Accumulate** CMP is 10% < Fair Value
  - Hold** Value = CMP
  - Lighten** CMP is 10% > Fair Value
  - Sell** CMP is 20% > Fair Value
- (CMP–Current Market Price)

**Group B**

Stocks without near term positive cash flows, history of losses, or at early stages commercialisation.

**Speculative Buy – Class A**

These stocks will have more than one technology, product or investment in development, with perhaps those same technologies offering multiple opportunities. These features, coupled to the presence of alliances, partnerships and scientific advisory boards, indicate the stock is relative less risky than other biotech stocks.

**Speculative Buy – Class B**

These stocks may have more than one product or opportunity, and may even be close to market. However, they are likely to be lacking in several key areas. For example, their cash position is weak, or management or board may need strengthening.

**Speculative Buy – Class C**

These stocks generally have one product in development and lack many external validation features.

**Speculative Hold – Class A or B or C**

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