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Companies covered: **ACW, Heximа Public Offer, OPT**

	Bioshares Portfolio
Year 1 (May '01 - May '02)	21.2%
Year 2 (May '02 - May '03)	-9.4%
Year 3 (May '03 - May '04)	70.6%
Year 4 (May '04 - May '05)	-16.3%
Year 5 (May '05 - May '06)	77.8%
Year 6 (May '06 - May '07)	17.4%
Year 7 (May '07 - May '08)	-35.8%
Year 8 (May '08 - May '09)	-7.4%
Year 9 (May '09 - May '10)	50.2%
Year 10 (May '10 - May'11)	45.4%
Year 11 (May '11 - May '12)	-18.0%
Year 12 (May '12 - May '13)	3.1%
Year 13 (May '13 - May '14)	26.6%
Year 14 (May '14 - May '15)	23.0%
Year 15 (May '15 - May '16)	33.0%
Year 16 (May '16 - May '17)	16.8%
Year 17 (May '17 - May '18)	-7.1%
Year 18 (May '18 - May '19)	-2.3%
Year 19 (May '19 - May '20)	39.5%
Year 20 (May '20 - Current)	57.9%
Cumulative Gain	1620%
Av. Annual gain (20 yrs)	19.3%

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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 Sets Clear Direction with Capital Raise

Actinogen Medical (ACW: $0.024) has received commitments of $6 million in a private placement plus a rights issue to follow which will raise up to an additional $4.6 million. Both raisings are being conducted at $0.022 per share.

The capital raising comes with a clear direction for its lead compound, Xanamem. Actinogen intends to start two Phase II studies with Xanamem, one in Alzheimer's disease (in patients with Mild Cognitive Impairment), and the second in patients with Fragile X syndrome (FXS).

In patients with FXS, elevated cortisol are linked to behavioural problems, general anxiety and memory. Xanamem decreases the production of cortisol in the body, which is a stress hormone.

To support its approach, Actinogen has completed multiple clinical studies of Xanamem, both in healthy volunteers and also a study in patients with mild Alzheimer's disease. Those results can be summarised as follows.

Previous Data Generated for Xanamem

Its most significant study to date was in 186 patients with mild Alzheimer's disease. That study, reported in May last year, failed to achieve statistical significance at the 10mg per dose. However the dose was found to be safe and it appears the dose was too low to achieve a meaningful impact.

Arguably, the dose needed to be twice as high in this adult population, as described previously in a scientific publication, but the dose was restricted following discussions with the FDA.

Following this study Actinogen reported results in October last year in a study in 42 healthy elderly volunteers at the 20mg a day dose. In the study, and using the Cogstate Cognitive Test Battery, it was found that cognitive improvement was achieved in three of the six measures over the 12 week treatment period. This included a statistically significant improvement in work memory, and also in visual attention with a trend to improvement in psychomotor function. The compound was found to be safe at the 20mg a day dose over the treatment period.

There was also a statistically significant reduction in cortisol levels in the active group over placebo. Overall, it was a meaningful result, particularly given the low numbers of subjects in this trial.

In a target occupancy study in 36 subjects (32 completed), with half having confirmed Alzheimer's disease, Xanamem was found to achieve between 50% - 85% occupancy (binding) to the target enzyme in the brain (11beta-HSD1) at doses of between 5mg-30mg per day over seven days.

Continued over

This growing body of evidence provides some confidence for proceeding to a further study in Alzheimer's disease patients. There are some key differences in this forthcoming study.

Phase II MCI in Alzheimer's Disease Study

As indicated the daily dose will be doubled. The treatment period will also be twice as long. This study will be conducted in Australia at 12 sites. And another important difference is that the patient population will be one stage less advanced, with MCI due to Alzheimer's disease (compared to patients with mild Alzheimer's disease).

Patients going into the study will also have confirmed elevated beta amyloid, either in the CSF (through a lumber puncture) or a PET scan, with both being invasive tests. Actinogen will assess the subjects for a number of cognitive impairments including with the Cogstate NTB. Cortisol levels will be measured at the start and during the study. A raft of new biomarkers will also be included as exploratory endpoints.

A total of 72 patients will be recruited, aged between 65-80. The study will start in the first half of next year and take two years to complete. It's a very well structured and detailed study.

Fragile X Syndrome Study

In H1 2021 Actinogen intends to start a smaller study in children with Fragile X syndrome (FXS). Around 40 adolescents 12-18 years of age will be enrolled in an investigator-initiated trial to be run in Melbourne at the Murdoch Children's Research Institute and the Royal Children's Hospital.

The dose to be used will be between 5mg-10mg per day. The patients will be treated for only 12 weeks, with the trial expected to be completed within 12 months from starting. Key efficacy endpoints will be improvements in sleep, anxiety, behavioural problems and daily living skills.

FXS is a smaller market, estimated at US$250 million a year in 2026 in seven key countries including the US, Germany and Japan. However, FXS it is an orphan drug indication which provides development benefits and lower trial sizes.

Summary

Actinogen has a key investor in biotech investment fund BVF which holds a 19% stake.

The capital raising underway together with the clear clinical direction being taken by the company and clinical data to date make this stock warrant investment consideration.

Other potential indications may be added to future clinical studies to be funded by grant funding or partners. This includes tackling cognitive impairment in patients with schizophrenia and diabetes.

Xanamem is an orally available drug candidate which broadens its appeal for use in other indications, if cognitive benefits can be demonstrated, coupled to an acceptable safety profile.

Including shares issued through the placement, Actinogen Medical is currently capitalised at $34 million.

Bioshares recommendation: **Speculative Buy 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 of 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

Sell

Corporate Subscribers: Cogstate, LBT Innovations, Opthea, ResApp Health, Pharmaxis, Dimerix, Adalta, Actinogen Medical, Patrys, Cyclopharm, Antisense Therapeutics, Imugene, Exopharm, Immutep, Neuroscientific Biopharmaceuticals, Invex Therapeutics, Anteris Technologies