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	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 - May '21)	86.8%
Year 21 (May '21 - Current)	5.2%
Cumulative Gain	2040%
Av. Annual gain (20 yrs)	20.7%

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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 –

Neuren Reaches Agreement with FDA for New Indication Studies

Neuren Pharmaceuticals (NEU: \$1.31) has reached agreement with the FDA for clinical study designs in new indications with its drug candidate NNZ-2591. There were some important points of agreement with the regulator that will allow more constructive trials to be conducted by the company.

NNZ-2591 is a synthetic analogue of a peptide that is normally found in the brain that activates IGF-1 levels and signalling pathways in neurons. It is easier to manufacture than its lead drug candidate, trofinetide, which has been licensed to Acadia Pharmaceuticals. It also has better bioavailability than trofinetide, which means that a lower dose is required, and has been shown to readily cross the blood-brain barrier.

Acadia is currently conducting a Phase III study with trofinetide in 184 girls and women with Rett Syndrome. Results from this study are expected in Q4 this year.

Neuren has selected three orphan indications for NNZ-2591. These are Phelan-McDermid syndrome, Angelman syndrome and in Pitt Hopkins syndrome. These are all neurological disorders with the aim to improve neuronal connectivity in the brain. They are each also due to genetic abnormalities, which means the conditions can be simulated in mice through genetic manipulation.

Managing Director of Neuren Jon Pilcher said that the results with NNZ-2591 were “fantastic” in all four animal studies with eight different tests conducted in each trial.

The key outcomes from the pre-IND meeting with the FDA includes testing immediately in children rather than adults first, and also longer studies, 13 weeks, which is the treatment period in the Phase III study being completed by Acadia in Rett syndrome.

Pilcher said the company has a much better understanding on the required dose in these studies, which will be much lower than the dose used with trofinetide in Retts syndrome. Rett syndrome is the most severe of the syndromes Neuren is seeking to treat.

The trials in Phelan-McDermid syndrome and Pitt Hopkins syndrome will be conducted in the US with the Angelman syndrome to be run in Australia (by Novotech). Pilcher expects recruitment into the Angelman syndrome study to be rapid with hundreds of patients with the disorder in Australia. Each trial indication will seek to recruit between 10 - 20 patients.

Neuren is capitalised at \$150 million and had \$22.6 million in cash at the end of March.

Bioshares recommendation: Speculative Buy Class A

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

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