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Bioshares

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

Companies covered: CUV,DXB,LBT,
NEU,PXS,RNO,TLX

Extract from Bioshares –

Biotech Stocks on the Move

Several biotech stocks have been making strong gains in their share prices over the last two months, reinforcing the sustained interest in the sector since the beginning of last year.

Since July 1, Rhinomed is up **110%**, LBT Innovations has gained **71%**, Dimerix is up **59%**, Pharmaxis' share price has increased by **46%**, Neuren Pharmaceuticals is up **37%** and Clinuvcl has gone up **31%**. The reasons for the price gains are mixed but highlights that stocks in the sector are readily responding to positive news flow.

Neuren Pharmaceuticals - Share Price Gains Speed Ahead of Phase III Results

Not surprisingly, Neuren Pharmaceuticals (NEU: \$2.23) has seen a strong rise in its share price in recent months with the readout of a major Phase III study with its lead drug candidate trofinetide due later this year.

That Phase III study, in patients with Rett syndrome, is being conducted by Neuren's partner Acadia Pharmaceuticals and has recruited 181 patients across 21 locations, all in the US. Last week Acadia announced it would now be starting another study in Rett syndrome in girls aged between two to five years. That trial will treat the girls with trofinetide for 12 weeks with a possible trial extension for a further 21 months.

The reason for conducting this study now is to allow a full New Drug Application (NDA) submission if the Phase III result is positive. The trial in children less than five years of age will only assess safety, as efficacy is difficult to measure due to the rapid progression of disease at that age.

Whilst the company is awaiting the results from the Phase III Rett syndrome study, it plans to initiate three Phase II studies with the second compound in development, NNZ-2591. Last week the company announced that an ethics approval submission has been made to conduct one of those studies in Australia, for Angelman syndrome. Whilst the study will be conducted at three sites in Australia, an Investigational New Drug Application (IND) was still filed to help facilitate any future development work for this indication in the US.

Neuren CEO John Pilcher expects rapid recruitment into the Phase II Angelman syndrome study, which will seek to enrol 20 patients who will be treated for 13 weeks. We expect this study to commence next month.

Neuren will also shortly file two additional INDs to conduct trials with the same drug candidate for the neurodevelopment disorders Pitt Hopkins syndrome and Philan-McDermid syndrome. These are all genetic diseases which has allowed Neuren to conduct preclinical studies with mice that are genetically altered to display the same disorder.

Continued over

	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)	19.5%
Cumulative Gain	2332%
Av. Annual gain (20 yrs)	20.7%

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Pilcher said that in all preclinical studies with NNZ-2591 the results were very consistent, where the knockout mice (that had been genetically altered to develop the target disease) returned to normal from treatment with NNZ-2591. Importantly there was no treatment effect in the control mice that had no genetic modifications.

Neuren has also identified a fourth indication for NNZ-2591 in Prader Willi syndrome. This program is around six months behind the other three Phase III programs.

By the end of this year, Neuren will have results from its Phase III study with trofinetide being conducted by Acadia Pharmaceuticals and three or potentially four Phase II study results in 2022 with NNZ-2591. These trials will not have a control/placebo arm. The aim of the studies will be to define the efficacy measures for a subsequent registration study if positive effects are detected in the Phase II trials.

Bioshares: Speculative Buy Class A

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Continued over

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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