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Bioshares

27 May 2019
Edition 793

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

Companies covered: **1AD, ANP, HMD, LBT, TLX**

	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)	-36%
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 - Current)	1.3%
Cumulative Gain	691%
Av. Annual gain (18 yrs)	16.0%

Bioshares is published by Blake Industry & Market Analysis Pty Ltd.

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Individual Subscriptions (48 issues/year)
\$470 (Inc.GST)
Edition Number 793 (27 May 2019)

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Extract from Bioshares –

Antisense Therapeutics Completes Recruitment in Phase II DMD Study

Antisense Therapeutics (ANP: \$0.051) has completed recruitment into its Phase II Duchenne Muscular Dystrophy (DMD) study being conducted at the Royal Children's Hospital in Melbourne.

Nine boys with advanced DMD have been recruited and are being treated with the company's exploratory drug candidate, ATL1102, which has proven activity as an anti-inflammatory agent from a Phase II study completed in multiple sclerosis. The patients are being treated for 24 weeks with ATL1102. Dosing will be completed in November, with the final two patients expected to begin treatment this month.

In the study, patients are being given a dose of 25mg/week, with three patients having completed the 24 week treatment. In the company's previous MS study with the same drug, a dose of 400mg/week for eight weeks was assessed. ATL1102 was found to reduce the cumulative number of new active lesions by 54% more than in the placebo group over the 12 weeks with 90% fewer new enhancing lesions than placebo at the end of the study. There were some treatment related side effects, although these were reversible after treatment ended. According to the company, published data on pharmacometric modelling of the drug for six months treatment of MS patients showed that activity of the drug should be observed down to around 60mg/week with the potential for activity at a lower dose in smaller patients, such as children.

Following regulatory consultant advice received by the company, Antisense Therapeutics is planning to seek approval to conduct a larger Phase II study (in DMD) in Europe in the same target indication next year, regardless of whether any positive efficacy signals are generated in the current trial, pending positive safety data. To date, no serious adverse events have been reported. That trial may explore larger doses of the drug and for longer periods, such as 12 months. If sufficient data could be generated in that study, from even less than 100 patients, then it may be sufficient for conditional approval. Antisense CEO Mark Diamond said "the company will seek scientific guidance from the European regulatory agencies on an appropriate trial design."

15th Bioshares Biotech Summit

26 - 27 July 2019

"The Competitive Landscape"

Two Locations this Year:

Friday at Skyline, Overlooking Queenstown and Lake Wakatipu
Saturday at the picturesque Millbrook Country Club
Strictly Biotech CEOs-Only Dinner on Thursday Preceding

www.bioshares.com.au/queenstown2019.htm

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The therapeutic hurdle for new treatments in DMD is very low, given the lack of effective treatments available in this disease area. In 2016, US biotech Sarepta Therapeutics achieved a controversial approval for its drug Exondys 51, which showed only a marginal benefit. The company submitted data to the FDA from a study in 12 boys with DMD. Exondys 51 is now on the market and generating annualised sales in the US of US\$350 million. Sarepta has a market value of US\$9.0 billion.

The rationale for trialing ATL1102 in treating DMD is that ATL1102 inhibits the biological target CD49d. The link between CD49d and DMD was uncovered by other researchers (<https://www.ncbi.nlm.nih.gov/pubmed/26664665>). In following 75 boys with DMD, it was found that those with higher levels of CD49d on their T-cells experience both a more rapid as well as a more severe progression of their disease. In Antisense's Phase II MS study, the results showed that T-cells expressing CD49d were reduced by around 25%. "CD49d was found to be an important biomarker as well as a potential immunotherapy target in DMD," said Diamond.

The researchers argued that blocking CD49d could be used as a therapeutic approach to treating inflammation-mediated tissue damage in DMD (i.e. stopping the boys' T-cells from infiltrating and damaging muscular function). The boys in the current DMD study are all wheelchair bound because of rapid muscle wasting characterised by this disease as a result of absence of the dystrophin protein that maintains muscle integrity.

Antisense held cash of \$3.7 million at the end of March. It is capitalised at \$21 million.

Bioshares recommendation: **Speculative Buy Class B**

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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

Sell

Corporate Subscribers: Cogstate, Bionomics, LBT Innovations, Opthea, ResApp Health, Pharmaxis, Dimerix, Adalta, Actinogen Medical, Patrys, Cyclopharm, Emvision, Antisense Therapeutics

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