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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 - Current)	68.6%
Cumulative Gain	1217%
Av. Annual gain (19 yrs)	18.8%

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# Bioshares

27 January 2020  
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*Delivering independent investment research to investors on Australian biotech, pharma and healthcare companies*

*Extract from Bioshares –*

## January Clinical Trials Update

### Antisense Therapeutics Outlines Phase II/III DMD Trial

Antisense Therapeutics (ANP: \$0.073) has completed a Phase IIa study in nine boys with Duchenne Muscular Dystrophy (DMD) with a positive safety profile and some early encouraging signs of efficacy with its drug candidate, ATL1102.

ATL1102 stops the migration of lymphocytes from the blood stream, through the endothelium to areas of inflammation in the body by inhibiting the receptor CD49d. In a Phase II study previously, the compound was found to be very effective in treating patients with multiple sclerosis, albeit at much higher doses (400mg per week for two months) and with some side effects.

### Phase IIa Trial Results

In the most recent trial in DMD, at a smaller dose (25mg per week) in children but for a longer period (six months), seven of the nine boys showed either an increase or no decline in their strength, as assessed by the PUL2.0 (Performance of Upper Limb Module) test battery. Of these, four boys displayed an improvement as measured by the PUL2.0 assessment, and three boys achieved an improvement in grip strength. The mean gain in this score was 0.9 points, compared to an expected mean decline of 1.09 points in boys at a similar age / stage of DMD disease.

### Phase IIb/III Study Design

Antisense provided details of its planned Phase IIb/III study which will be conducted in Europe. The study will have three arms, comprising of a placebo, and two doses of ATL1102, potentially involving a higher dose, delivered weekly over a year. The study will involve 75 boys at a similar stage of disease, with 25 boys per arm.

Pending the quality of the results, the trial may be sufficient to file the compound for approval in Europe following guidance from three European regulatory authorities. The primary efficacy endpoint will be the PUL2.0 test battery.

Following the one-year treatment, all boys in the trial will be offered to continue in an extension study on the highest safe dose tested.

The muscle wasting that characterises DMD is believed to be accelerated by excessive inflammatory action by the immune system. It has been found that boys with DMD who have higher levels of T-cells expressing elevated CD49d experience more rapid deterioration of their condition.

### Other Indications

Although ATL1102 was found to deliver similar efficacy levels as the Biogen drug Tysabri (annual sales of US\$1.8 billion), with no evidence of causing the fatal PML (progressive multifocal leukoencephalopathy) that Tysabri carries (4.2 in 1,000 patients

*Cont'd over*

with 75% survival), the FDA has restricted the dose to 25mg a week with any further MS studies at this point. More information on the safety profile of ATL1102 in the DMD studies could allow higher doses to be explored in MS.

Antisense is also exploring other autoinflammatory conditions that are impacted by high CD49d T-cell levels. The company will explore available grant funding for orphan indications. It holds sufficient drug material to conduct such studies.

### **Summary**

Antisense Therapeutics is capitalised at \$36 million. At the end of September last year the company held cash of \$2.0 million, with an additional \$5.5 million raised last month through the exercise of options.

*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 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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