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Bioshares

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Edition 680

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

Extract from Bioshares –

More Positive Results for Adalta

The CEO of Adalta (1AD: \$0.22), Sam Cobb, was also in San Francisco this month for meetings surrounding the JP Morgan biotech event. Cobb was there with results in hand from more positive preclinical results around the company's anti-fibrosis treatment. Cobb had 30 meetings, split evenly between potential partners and investors/analysts.

Adalta listed on the ASX in August last year, raising \$10 million at 25 cents a share. Its core technology is around a new generation of antibodies called i-bodies, the shape of which has been derived from shark antibodies. Adalta has found that the shape of the non-binding scaffold is almost identical to human antibodies. Being mostly human in appearance, they have a reduced risk of generating an immune response in human therapeutic use. Cobb said that no one would have thought that the shape would be the same and this discovery underpins the company's technology.

The i-bodies also have a long binding loop that is not found on human antibodies. The combined features of these compounds mean that they have a high specificity like all antibodies, but can act like small molecules because of the long binding loop reach. They are very stable including at high temperature and low pH, and are very inexpensive to manufacture compared to monoclonal antibodies.

The i-bodies are 10% of the size of human antibodies with no glycosylation (required), thereby making them easier and cheaper to make. The first hurdle for the company this year is to complete manufacture of its lead candidate i-body, which is made in an e-coli production system. Manufacturing started in August last year and is due to be completed in Q1 this year.

The next major hurdle for the company is to conduct toxicology testing for its lead compound, which will be a key event given it represents a new generation antibody. Cobb said the corporate discussions (with biotech/pharma groups) will start to get serious once the company has passed the toxicology results hurdle.

Preclinical results just out....

Lung disease in mouse model

In the Bleomycin mouse model, the company's i-body drug candidate, AD-114, was tested to see if it can prevent and treat lung fibrosis (idiopathic pulmonary fibrosis or IPF). In this model, mice are given the toxin Bleomycin which creates collagen build up in the lungs. Mice prophylactically given AD-114 showed a clear response of reduced collagen content and inflammation.

According to what is called an Ashcroft Score, there was a significant reduction in this measure when AD-114 was given both prophylactically and therapeutically. AD-114 works by binding to CXCR4 on fibrocytes. Fibrocytes that express CXCR4 are more likely to migrate to the lungs and it has been found that patients that progress more rapidly in IPF

Cont'd 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)	-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 - current)	28.7%
Cumulative Gain	848%
Av. Annual gain (14 yrs)	19.4%

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express more CXCR4. That a good result has been achieved in a mouse model is very encouraging given that AD-114 should be more specific to CXCR4 on human tissue than mouse tissue.

The Bleomycin model is the gold standard for the FDA, with the regulator keen to see therapeutic data.

Liver disease mouse model

In the liver disease model, mice were given a different toxin (streptozotocin) and then fed a high fat diet for six weeks, before being treated with AD-114 for 21 days. The result released earlier this month was that a decrease in ALT levels (a biomarker of liver disease) and a decrease in the non-alcoholic liver disease score was achieved. There was also a significant reduction in hepatocellular ballooning. These findings suggest that Adalta's drug candidate may have a potential in the treatment of NASH through antifibrotic activity.

Previous preclinical data in eye disease

Adalta has previously shown in a mouse model for fibrotic eye disease that AD-114 can reduce retinal lesion size following damage and reduce contraction of the retina.

Summary

Adalta has now shown in three mouse models that its drug candidate AD-114 has activity in therapeutic applications in fibrotic-mediated diseases associated with the lung, liver and eye. Antifibrotic agents that show consistent activity across a number of disease models have shown to be attractive assets to pharmaceutical companies in recent years. Completion of toxicology studies this year and Phase I safety studies next year may position the company well for a major transaction in 2018.

Adalta is capitalised at \$17 million. The company had \$9.8 million in cash at the end of September last year.

Bioshares recommendation: **Speculative Buy Class A**

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 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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