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Bioshares

7 March 2014
Edition 542

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

Extract from Bioshares –

Viralytics Starts Phase I/II Storm Study With Intravenous Cavatak

Viralytics (VLA: \$0.315) this week announced it had started a 30 patient Phase I/II study (called STORM) in the UK with its investigational cancer therapy, Cavatak. This comes on the back of a \$27 million capital raising recently which has transformed the company.

Viralytics previously had a largely retail shareholder base. Following the capital raise, the company is now 45% owned by institutional investors, including some 'big name' biotech investors from the US according to CEO Malcolm McColl.

Phase II CALM trial results

Viralytics has completed enrolment in a Phase II study (CALM) with Cavatak, which uses a virus to attack cancer cells. The virus used is Cocksackievirus A21, which is an unaltered form of the common cold. There is a theory that spontaneous remission in some cancer patients has potentially been due to infection of the common cold.

The results from the Phase II study have been very impressive, matching those achieved by Amgen with its oncolytic virotherapy, which was acquired through a US\$1 billion deal.

The latest data shows that 35% of patients reached the six month immune related progression-free survival at 6 months. And 60% of patients were alive at 12 months. This is a very good result, given most patients with Stage III/IV melanoma are not expected to live out a year.

This week the company also announced that these results will be formally presented at the American Association for Cancer Research next month by the Principal Investigator of the trial, Dr Robert Andtbacka. What is new is that the company indicated that Dr Andtbacka will focus on the activity in non-injected metastatic tumours, something the company has talked little about.

The way the trial was conducted was that tumours were directly injected with the virus.

Cont'd over

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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 - Current)	60.9%
Cumulative Gain	473%
Av. annual gain (13 yrs)	20.0%

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

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Individual Subscriptions (48 issues/year)
\$400 (Inc.GST)
Edition Number 542 (7 March 2014)
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That causes lysis, which destroys that tumour. However, the therapy is meant to work by attacking distant tumours as well, by initiating an immune response against other non-injected tumours. If this therapy is to be of commercial relevance, then it will need to show strong activity against distant tumours.

Phase I/II STORM Study

The STORM study just started is important for two reasons. The first is because the company will look at four different solid tumours: late stage melanoma, prostate, lung and metastatic bladder cancer. The first part of the trial will look at Cavatak alone, and see which types of tumours the virus is attracted to most.

The second relevant part is that this study will involve an intravenous delivery of Cavatak, rather than being injected directly into a tumour. Once the preferred type of tumour is select, the second part of the trial will focus on patients with that type of tumour and combine that treatment with the preferred chemotherapy regime.

An effect on efficacy is expected in the second phase of this trial. If this trial is successful, with results expected from early 2015 to 2016, then it has the potential to expand the market opportunity for this product.

Phase II Randomised Study

In the second half of this year, Viralytics will start a randomized study with Cavatak in patients with advanced melanoma. The difference between this study and the CALM study is that this trial will include a control arm to objectively assess the benefit of this treatment. It is expected to take around three years to complete.

Summary

Viralytics is now capitalised at only \$57 million but holds \$27.5 million in cash following completion of the capital raising, which this week received shareholder approval.

Cancer immunotherapy is a hot area of drug development which supports the recent interest behind Viralytics. Healthcare investment bank Leerink Swann believes that a half of all cancer therapies over the next decade may involve immunotherapy. And the editors of *Science* magazine chose cancer immunotherapy as 'The Breakthrough of the Year' in 2013.

Viralytics is following the path of Amgen with its T-Vec virotherapy approach. Potentially both therapies could be used sequentially in the treatment of melanoma and other solid cancers.

Important milestones ahead for Viralytics are:

- Presentation of CALM study at AACR (April) with results on distant tumours important
- Top line results from CALM study (Q3 2014)
- Start of randomized Phase II study (2h 2014)
- Survival data from CALM study (Q1 2015)
- Initial data from STORM study (Q1 2015)

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 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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