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Bioshares

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

Companies covered: ACR, ALT, NAN, PNV, VLA

	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 - current)	8.6%
Cumulative Gain	**389%**
Av. Annual gain (14 yrs)	**16.7%**

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Extract from Bioshares –

US Investors Take Note Of Viralytics

Viralytics (VLA: $0.46) has seen a strong run in its share price in the last two weeks, increasing by 58%. The increased interest in the stock has been due to a US research report on the company by Roth Capital Partners. It was an unsolicited report on the company which included a 12 month price target of $3.84 a share for Viralytics.

We have previously identified the company as one of the most undervalued biotech stocks on the ASX. It looks like others now agree. The report estimates peak sales of CAVATAK of US$475 million for the treatment of melanoma, giving the program a 40% chance of delivering a marketed product.

Drivers of the stock price are expected to be clinical progress in the CAVATAK programs, as well as increased attention in the oncolytic virus space, with Amgen's T-Vec due to be considered by an FDA Advisory Committee on 29 April.

In our view, a positive outcome for T-Vec will be beneficial for Viralytics, with increased attention in this field of cancer drug development, where there are very few advanced programs. Amgen acquired the rights to T-Vec in a US$1 billion deal in 2011 with Biovex.

In its 400 patient Phase III trial, T-Vec delivered an overall survival benefit of 4.4 months. However, the result just missed achieving statistical significance with this secondary endpoint with a p-value of 0.051 (p less than 0.05 is considered statistically significant). On the primary measure of durable response, this was achieved in 16% of patients, compared to 2% in the control arm. This result was statistically significant.

Viralytics has achieved comparable data with CAVATAK to T-Vec in respective Phase II programs.

The question for the Advisory Panel is whether one Phase III trial, which narrowly missed showing a statistically significant survival benefit, is enough to allow the drug to pass through to market. Given its very favourable safety profile, and the apparent willingness by the FDA to bring new therapeutics to market more quickly for unmet or poorly served clinical needs, it's possible that the drug will get through, giving patients another therapeutic option.

Cont'd over

– Viralytics cont'd

The reality is that the drug will likely be used as a combination therapy with the new checkpoint inhibitors that are now on the market. Amgen has conducted a Phase Ib trial combining T-Vec with the checkpoint inhibitor Yervoy which showed a 56% reduction in tumours with no added toxicity when T-Vec was added. It has also started a combination trial with T-Vec and Keytruda, another checkpoint inhibitor.

A decision to not approve T-Vec at this point by the FDA could also be beneficial to Viralytics, bringing Viralytics closer to Amgen with respect to development progress. However, using different viruses to treat melanoma and other cancers, the two products are no necessarily mutually exclusive in a clinical setting.

Viralytics is capitalised at $85 million with $25 million in cash at the end of last year.

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 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, Impedimed, LBT Innovations, Tissue Therapies, Viralytics, Phylogica, pSivida, Benitec BioPharma, Admedus, Calzada, Invion, Imugene, Analytica, Circadian Technologies, Reproductive Health Science, Regeneus, Innate Immunotherapeutics