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Bioshares

28 November 2014
Edition 579

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

Companies covered: IVX, VLA, Genetic Signatures IPO Profile

	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)	6.5%
Cumulative Gain	**380%**
Av. Annual gain (14 yrs)	**16.6%**

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Extract from Bioshares –

Viralytics – An Overlooked Investment Opportunity

Viralytics (VLA: $0.315) is a seriously undervalued biotech stock, at a time while it is working in the field of immuno-oncology where there is substantial interest from biotech and pharmaceutical companies.

Immunotherapy treatments in the cancer field represent a major breakthrough in the fight against cancer. One investment bank, Leerink Swann, is predicting that in the next decade, half of all cancer treatments could involve immunotherapy.

Some immunotherapies can offer significantly better safety profiles than chemotherapy treatments as well as generate very effective results as well.

In September Merck launched its anti-PD1 drug Keytruda in the US. Keytruda is a checkpoint inhibitor and is forecast to generate sales of $6 billion by 2025.

It is believed by some that combination therapies in this area will be the basis for the more effective treatments. Viralytics has shown in mouse studies that combining its drug candidate CAVATAK with an anti-PD1 antibody delivered a far greater response in a very aggressive cancer model.

The results showed that over a certain time, the combination of CAVATAK with the anti-PD1 antibody achieved a tumour free result in 75% of mice, compared to 0% in the anti-PD1 antibody alone.

Big Pharma Interest in Cancer Immunotherapy

Many of the large biotech and pharmaceutical companies have active cancer immunotherapy programs. Amgen acquired oncolytic virotherapy company Biovex (which was developing a benign form of the herpes virus) in a deal worth up to US$1 billion. (Oncolytic virotherapy is the same approach being tried by Viralytics but using the *Coxsackievirus.*)

Amgen's drug candidate T-Vec has completed Phase III studies, and has the potential to be used in combination with CAVATAK in the future. The results from a Phase II study in melanoma with CAVATAK compare favourably with T-Vec Phase II data.

Pfizer struck a deal this month with Merck KgaA in Germany to gain access to that company's anti-PD-L1 antibody. The alliance will see up to 20 clinical programs commence next year, which will be pairing the Merck drug candidate with a portfolio of Pfizer drugs and drug candidates. Phase I interim data with the anti-PD-L1 antibody from a 550 patient trial has been reported and the program is in a Phase II study.

Cont'd over

Pfizer paid Merck an upfront payment of US$850 million, with a further US$2 billion in milestone payments. "Immuno-oncology is a top priority for Pfizer," said a Pfizer spokesman. (A table of selected PD1, PDl-1 and CTLA-4 antibodies in development can be found in *Bioshares* 574, p3.)

Bristol Myers-Squibb has had its anti-CLA4 inhibitor Yervoy (CTLA4 down-regulates the immune system) on the market since 2011 and in 2013 the drug generated sales of US$960 million. Roche, GlaxoSmithKline and AstraZeneca are also active in the cancer immunotherapy space.

Funded to Explore Multiple Clinical Studies

In March this year, Viralytics raised $27 million, predominantly from specialist US biotech funds. This dramatically changed the share registry of the company from a 100% retail base to now 46% being held by institutions. Those funds raised will allow the company to conduct multiple clinical trials with CAVATAK, both as a standalone treatment and in combination with checkpoint inhibitors and CTLA-4 inhibitors (and/or other recently approved cancer drugs). With a vastly improved shareholder base, the company presumably will have access to additional funds from its institutional shareholders, should they be required.

CANNON Study – Bladder Cancer – to Start Q1 2015

In the first quarter of next year, Viralytics intends to start a Phase one study with CAVATAK in patients with early stage bladder cancer. The study will be conducted in the UK. CAVATAK will be used in a frontline setting before surgery, with and without chemotherapy. There is a strong need for more effective and safer therapies in this indication. The trial will recruit up to 30 patients.

STORM Phase I/II Study, Solid tumours, IV formulation
Initial results in Q1 2015

In March this year a Phase I/II study in patients with solid tumours was started using an intravenous for of the therapy (rather than injecting directly into the tumours).

The aim with this trial is to see if the CAVATAK can be delivered intravenously. If it can, then it will expand the potential market for the therapy. The study will enroll 30 patients in the UK, with preliminary results early next year and final results in early 2016.

CALM study (completed)

The interest in Viralytics stems from the positive Phase II results in 57 patients with late stage melanoma. In this trial, one year survival was 73%, compared to 58% for T-Vec in a similar Phase II trial. In this trial, importantly, CAVATAK was shown to be effective at the injected tumour, but also at distant tumours, although specific details for its effect on distant tumours has not been released.

Final survival data from the CALM study is expected in Q1 2015. The company is now planning follow-on trials with CAVATAK, both as a monotherapy an in combination with PDL1 and other leading cancer immunotherapy drugs.

Viralytics is capitalised at $58 million, and had $23.7 million in cash at the end of September.

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

Corporate Subscribers: Cogstate, Bionomics, Impedimed, QRxPharma, LBT Innovations, Tissue Therapies, Viralytics, Phylogica, pSivida, Benitec BioPharma, Admedus, Calzada, Invion, Imugene, Analytica, Circadian Technologies, Reproductive Health Science