

In this edition...

The novel therapy we discuss this week is based on the application of certain common, generally harmless viruses to lyse (break apart) tumour cells and then initiate an immune response. The interest here is that it may do well in addressing cancer that has spread throughout the body. The approach has gained momentum, lead by US company Biotech and locally by Viralytics.

And with biotech stocks experiencing weakness, we have put together a shopping list of five stocks to accumulate at more than attractive prices. A common feature is that all these companies are well funded and generally have a multiple shots on goal.

The Editors

Companies Covered: ACR, BTA, SRX, SPL, UBI, 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)	70.0%
Year 4 (May '04 - May '05)	-16.3%
Year 5 (May '05 - May '06)	77.8%
Year 6 (May '06 - May '07)	17.3%
Year 7 (May '07 - May '08)	-36%
Year 8 (May '08 - May '09)	-7.3%
Year 9 (May '09 - May '10)	49.2%
Year 10 (May '10 - Current)	-2.5%
Cumulative Gain	182%
Av Annual Gain (9 yrs)	18.5%

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Bioshares

11 June 2010
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Delivering independent investment research to investors on Australian biotech, pharma and healthcare companies.

Viralytics Plans for Phase II with Cancer Killing Virus

A Turbulent History

Viralytics (formerly Psiron)(VLA: 4 cents), has had a turbulent period in recent years. Its focus for many years was on the development of anti-inflammatory therapies and it had previously owned a 5% stake in **CBio**, a Brisbane-based biotech company developing anti-inflammatory drugs which earlier this year listed on the ASX. When CBio was a private company, Viralytics stock was used as a play to gain access to CBio with expectations of a major drug development deal.

This expectation saw Viralytics share price (then Psiron) reach in excess of 15 cents a share. The virotherapy technology, which uses viruses to attack cancer cells, is now the sole focus of Viralytics, with intellectual property assigned from the **University of Newcastle** in December 2006 by issuing 15.5 million shares. In that same month the company's name was changed from Psiron to Viralytics to reflect its core direction.

On 27 December 2006, CBio announced that a 'forecast transaction' with a large international pharmaceutical would not proceed. This sent the Viralytics share price into a downwards spiral. That was compounded with CBio selling down its stake in Viralytics, which at one point reached 15%, and finally sold out completely by November 2007. Another major shareholder, ATIF **Australian Technology Innovation Fund** (ATIF), also started selling down its stake in March 2007 causing more downward pressure on the share price. Viralytics sold most of its stake in **Analytica Ltd** in 2008, and Viralytics also sold the rest of its shares in CBio in 2010 after CBio listed.

A More Stable Share Register and Turnaround Begins

The movement in the Viralytics share register has now been stable for the last year, with the related parties having exited their related interests.

In April 2006, Viralytics appointed Bryan Dulhunty as executive chairman with long standing directors Stephen Jones and Wolf Hamisch departing the board. In July 2007 Phillip Altman was appointed to the board. Then in the second half of 2008 Paul Hopper was appointed non-executive chairman, Peter Molloy (ex-**Biota Holdings** CEO) was appointed director, Bryan Dulhunty took on the role of CEO and Managing Director, and Darren Shafren departed from the board to take up the role of Chief Scientific Officer.

In December 2007 the company raised \$1.2 million through a placement and SPP. And in June 2009 the company secured ongoing financing through a US\$6 million convertible note with **La Jolla Cove Investors**, which gives the company two year's of funding.

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Competition

A significant period for oncolytic virotherapy occurred in second half of 2008, when a competitor achieved very positive Phase II results using this type of therapy.

Biovex

Why the interest in oncolytic therapies? In June 2008 private biotech **Biovex** (Woburn, Massachusetts) produced some stunning results in a Phase II trial in 50 patients with inoperable Stage IIIc/IV melanomas. Patients with this stage of disease have a median life expectancy of only six months.

The target efficacy endpoint agreed to with the FDA was to achieve only objective responses or stable disease in two patients. Remarkably, 10 patients showed complete clinical response! Another four patients achieved a partial response (greater than 30% reduction in disease burden) with 10 other patients achieving stable disease. The therapy had no serious side effects. Overall survival was 52% at two years. Also of significance was that distant tumours (i.e. tumours that had not been injected with the virus) had also receded.

This result helped the company raise US\$70 million in 2009, the second largest VC capital raising last year. The company is now conducting a Phase III trial in metastatic melanoma, with only one pivotal study required by the FDA under an SPA (Special Protocol Assessment). The company uses a gene deleted herpes virus to destroy the tumour cell. The virus also encodes human GCSF and releases tumour antigens to help activate the immune system to attack cancer metastases.

In an earlier Phase I trial by Biovex in nine patients with solid tumours, two patients achieved stable disease. In this trial two to three injections were given directly into the tumour nine weeks apart. The best result was in melanoma tumours.

Viralytics Clinical Results

In May 2007, a Phase I trial with Viralytics' oncolytic virotherapy technology was started. In January this year final results were released. The trial involved nine patients with advanced metastatic melanoma. Patients were given a single injections of the virus directly into one tumour lesion on multiple occasions.

The therapy was shown to be very safe with no serious adverse events. In three of the patients the tumours reduced in size and in a further two patients the tumours remained stable. Also of interest was that distant tumour sizes measured showed that overall disease was stabilised in two patients from only infecting the one tumour lesion. The theory is the tumour becomes a virus factory, with replicating virus leaking out to the blood stream to start attacking other tumours and stimulating the immune system to destroy metastatic cancer cells.

So in what was a very positive Phase I study, five of the nine patients with advanced melanoma disease achieved a reduction or stabilisation of their tumour from the one injection into the one lesion given on multiple occasions in up to two different doses. These patients had failed or rejected all standard therapies.

What is Oncolytic Virotherapy?

Oncolytic therapy uses a virus injected directly into solid tumours which after destroying the solid tumour also spreads and also harnesses the immune system to destroy metastatic cancers around the body. It has now been shown by Viralytics that melanoma cells die because of the mechanical disruption caused by the massive viral replication and the programmed cell death triggered by the virus. Viralytics' virus attaches to two receptors, ICAM-1 and DAF, found on tumours, particularly melanomas, and which are not found in significant levels on healthy tissue.

Advantages of the Viralytics Virus

The limiting factor in oncolytic virotherapy is the production by the body of neutralising antibodies to the virus. Biovex uses a herpes virus and one of the disadvantages of that virus as an oncolytic virotherapy is that between 85%-90% of patients have been exposed to that virus previously.

Viralytics deploys the Cocksackievirus. Only about 25% of the population have had previous exposure to this virus and have circulating antibodies. All the patients in the company's trials are selected for a serum negative response to these antibodies. With oncolytic virotherapy, there is a two week window for the most effective treatment when the patients remain immuno-naïve.

Phase II Study

Viralytics is currently planning a Phase II study with its oncolytic virotherapy. The company has a pre-IND meeting with the FDA this month and following that meeting will submit its IND which will allow it to commence clinical studies in the US.

The Phase II study will be more aggressive than the Phase I trial completed. It's expected patients will be given multiple injections in multiple tumour lesions on multiple occasions. In Biovex's 50 Patient Phase II trial in patients with advanced melanoma, recruitment took two years to complete and similar time frame can be expected for Viralytics.

This trial is also expected to include the biopsy of distant tumours to better measure the effect of the therapy in other tumours spread throughout the body. Being a single arm study, there is the potential for interim trial results to be released.

Other Trials

Viralytics is currently conducting a Phase I trial in patients with head and neck cancer. The first three of nine patients have completed treatment. Following safety review, the trial will move to the next three patients, who will receive three injections into the tumour, rather than one in the first group. The third group of patients will receive six injections.

The Cocksackievirus is generally a virus that effects the respiratory system. It may then be suitability for treating respiratory linked tumours such as lung cancer. The company is currently considering whether a lung cancer study will also be investigated.

Viralytics also has intellectual property around the echovirus and there is the potential for a preclinical licensing deal around this technology.

Risks

The main medium term risk for the company is recruitment into the Phase II clinical study. The company will use a clinical research organization to co-ordinate this trial.

Another risk is that if the trial recruitment is slow, funding may become an issue. Currently the company has access to two years of funding.

Success from the Biovex Phase II trial in treating patients with advanced melanoma should assist in attracting interest from oncology physicians to participate in this trial.

Potential for Use with other Therapies

With activation of the immune system (within two weeks) being the limiting factor on oncolytic virotherapy, it's expected the combination of oncolytic virotherapy with other drugs that can lower the immune response to the infecting cancer attacking virus would help increase the efficacy of this treatment. This is an approach that is also likely to be explored in this field. It is believed that tumours treated with such viruses may also be much more susceptible to radiation therapy.

Summary

Over 1,000 patients worldwide have been treated with cancer killing viruses. Viralytics' CSO Darren Shafren says there is no doubt that the Coxsackievirus kills cancer cells.

It has been a long road to bring the Viralytics technology to this point. Corporate instability has been a major obstacle and that now appears to be resolved. The company has achieved initial clinical success and the very positive international Phase II data achieved by others is paving the way for Viralytics and the other groups in this sector.

Oncolytic virotherapy is showing strong potential as a safe and effective treatment for patients with solid tumours, even for those with end stage disease with no existing treatment options.

Viralytics has eliminated one of its biggest challenges in this market, that of funding, with sufficient cash for the next two years. Viralytics is currently capitalised at \$18 million.

Convertible Note

In June last year Viralytics secured financing through a convertible note with **La Jolla Cove Investors**. The financing involves four convertible notes, each worth US\$1.5 million. There is an automatic draw down each month of US\$250,000.

To date around \$3 million has been drawn down and converted to shares. We assume the shares have been sold on market with no substantial shareholder notice issued by La Jolla Cove Investors. The notes attract a 4.5% interest payment based on the outstanding amount. The notes can be convertible to shares by La Jolla Cove at an 18% discount to the weighted average market price of VLA shares.

With La Jolla Cove Investors continually selling down, it means there is a continued monthly selling pressure on the stock worth US\$250,000.

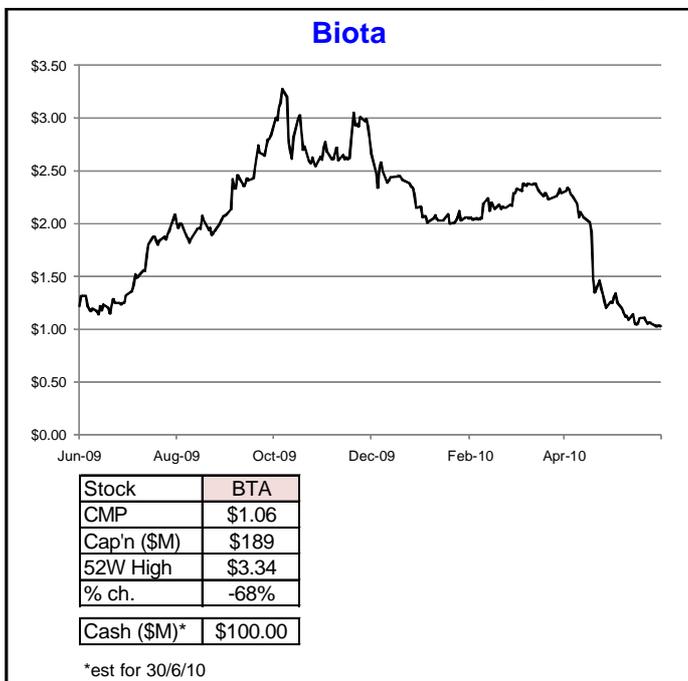
Funding Access

At the end of March the company had \$3.3 million in funds with access to between \$4.8 million - \$6.2 million through the conversion of options (by 29 June 2010) or the convertible note facility.

The company raised \$3.7 million in first quarter of this year from a placement (\$1.5 million), the convertible note draw down (\$1.6 million) and exiting from its CBio holding (\$0.5 million).

Biotech Shopping List – Five Stocks Worth Accumulating in the Weakened Market

A reader suggested last week that we construct a shopping list of stocks to pick up in the current down turn. We have a selection of five stocks, including Biota, Sirtex Medical, Universal Biosensors, Starpharma and Acrux. What characterises these stocks is a strong funding position and with the exception of Sirtex Medical, multiple shots at goal based on business model design (Biota) or platform technology (Universal Biosensors, Acrux and Starpharma).



Biota – A Buy at a Buck

Biota has experienced a dramatic decline in its share price from a rolling year high of \$3.34. Biota is stock that is subject to lumpy government orders for Relenza and seasonal usage of influenza medicines.

Biota's lustre, it could also be argued, has suffered as a result of several product handbacks received in the last 12 months, namely the HCV program from Boehringer Ingelheim in May this year and the RSV compound BTA9881 from AstraZeneca in August 2009. A lack of perceived action on the partnering of the Rest-of-World rights for LANI may have also disappointed. However, partnering should never be done in haste.

What has most appeal about Biota, however is its estimated cash position, which is expected to be in excess of \$100 million June 30. Biota may have some tax to pay for profits generated for FY2009. However, it is in a very strong position to support its drug development programs.

Bioshares recommendation: **Speculative Buy Class A**



Sirtex Medical – Attractive Buying at ~\$5.00

Without doubt, Sirtex Medical represents a very attractive buying opportunity at its current price. After peaking at \$8.05 in January, the stock has lost almost 40% in value.

Exchange rate movements have had some influence on this stock. However, a better measure of performance is based on Sir-Spheres unit sales, which were up 15% in the nine-months ending March 31 over the previous corresponding period. It is the long term growth trend in Sir-Spheres treatments that matters, which currently sit at very low rates of penetration in the liver cancer market.

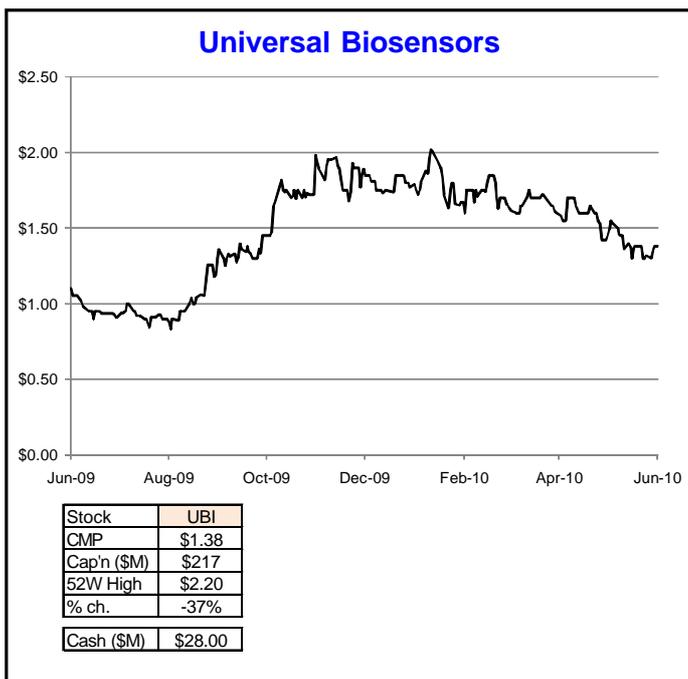
Calendar year 2011 may see a significant up-lift in Sir-Sphere sales, once the facility in Singapore commences selling product from the facility in May 2011.

The strategic significance of a plant in Singapore should not be underestimated, with logistics managed out of one of the globes premier transport hubs and opening up North Asian markets with timely and reliable supply of a time-decaying treatment. Furthermore, Singapore can serve as a product source for markets on the west coast of the USA.

Sirtex has not been helped by its Australian supplier of radiation services (ANSTO, Lucas Heights), which recently increased its prices for all customers by 100%.

Bioshares recommendation: **Buy**

– Cont'd over



Universal Biosensors – J&J Goes Public on OneTouch Verio

Universal Biosensors is a company with a broad horizon of opportunities that arise from its point-of-care diagnostic technology platform.

A significant event for the company was a public announcement (at least to the US investment world) by development and marketing partner, **Johnson & Johnson's Lifescan**, of the blood glucose test meter, One Touch Verio, at its recent Medical Devices and Diagnostics business review.

One Touch Verio was launched in Europe earlier this year and is scheduled for a US launch later in 2010.

According to J&J's presentation, One Touch Verio is positioned as a new platform that will "help patients gain further accuracy and insight". This is the first time that J&J has publicly discussed the product that has arisen from its collaboration with UBI.

The MD&D event was commented on in analyst reports prepared by **Citigroup Global Markets** and **Morgan Stanley** among others. One of these analysts picked up on the GDH-PPQ problem that is addressed by One Touch Verio and has emerged as a concern at the FDA. Test meters that use GDH-PPQ strips are not sensitive to different blood sugars and could give false readings. (See *Bioshares* 356).

Bioshares recommendation: **Speculative Buy Class A**



Starpharma Holdings – Benefits of a Platform Play

The shares of Starpharma Holdings have fallen by 31% off their 12 month rolling highs, with the company now capitalised at \$129 million. Starpharma is exploiting a platform technology based on the synthesis and design of large molecules called dendrimers. These molecules can be engineered to piggy-back other active molecules.

The company has numerous alliances, partnerships and collaborations, but is also about to commence under its own management, a clinical development program of Vivagel for the treatment of bacterial vaginosis (BV). Vivagel is currently being developed as a microbicide, and is funded by the US NIH with greater than \$26 million in committed support.

BV an attractive development concept because of its low program cost and is pitched a market that is poorly served by medicines that generate related sales of US\$300 million. Starpharma estimates the Phase II and Phase III program will cost \$9-\$10 million, and take two years to complete.

One important backdrop to these and other human health programs, is a royalty revenue stream that is expected to commence in CY 2011 from its condom coating deals, one with **SSL International**, the other with an unnamed partner. The company estimates that its could receive significantly more than \$100 million in royalties and payments.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares Model Portfolio (11 June 2010)

Company	Price (current)	Price added to portfolio	Date added
Sunshine Heart	\$0.033	\$0.036	June 2010
Biota Holdings	\$1.06	\$1.09	May 2010
Tissue Therapies	\$0.17	\$0.21	January 2010
QRxPharma	\$1.15	\$0.25	December 2008
Hexima	\$0.25	\$0.60	October 2008
Atcor Medical	\$0.14	\$0.10	October 2008
CathRx	\$0.20	\$0.70	October 2008
Impedimed	\$0.60	\$0.70	August 2008
Mesoblast	\$1.87	\$1.25	August 2008
Circadian Technologies	\$0.60	\$1.03	February 2008
Patrys	\$0.12	\$0.50	December 2007
Bionomics	\$0.30	\$0.42	December 2007
Cogstate	\$0.25	\$0.13	November 2007
Sirtex Medical	\$5.05	\$3.90	October 2007
Clinuvel Pharmaceuticals	\$0.25	\$0.66	September 2007
Starpharma Holdings	\$0.54	\$0.37	August 2007
Pharmaxis	\$3.05	\$3.15	August 2007
Universal Biosensors	\$1.38	\$1.23	June 2007
Probiotec	\$1.38	\$1.12	February 2007
Acrux	\$1.87	\$0.83	November 2004
Alchemia	\$0.56	\$0.67	May 2004

Portfolio Changes – 11 June 2010

IN:
No changes.

OUT:
No changes.



Acrux – Share Price off 28%

Acrux has developed the Axiron testosterone product, which involves the delivery of testosterone through the skin, applied under the arm. In this case, the product has been developed for men with testosterone deficiency. (The company has a similar product in development for women, called Luramist.)

In March, Acrux signed **Eli Lilly** as the global marketing partner for Axiron. Deal terms included a US\$50 million upfront, followed by another US\$3 million on the transfer of manufacturing assets. Conditional on the FDA approving Axiron, Acrux stands to receive US\$87 million. Once sales commence, another \$US195 million in sales related milestones could be received.

We estimate royalties to be in the high teens/low twenties.

Our valuation of Acrux (see *Bioshares* 352) placed a value of \$3.95 on each Acrux share at the time of the deal, with all assumptions largely remaining the same since that time.

Bioshares recommendation: **Speculative Buy Class A**

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.

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: Pharmaxis, Starpharma Holdings, Cogstate, Bionomics, ChemGenex Pharmaceuticals, Circadian Technologies, Biota Holdings, Halcygen Pharmaceuticals, Impedimed, QRxPharma, Patrys, LBT Innovations, Hexima, Tyrian Diagnostics, Mesoblast, Atcor Medical, CathRx, BioMd, Tissue Therapies, Viralytics

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