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Bioshares

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

In this edition...

Whilst biotech stocks are being hardest hit during these times of financial volatility and uncertainty, the sector is going from strength to strength, with the latest measure being the interest from international pharmaceutical companies at this year's AusBiotech conference.

Companies in the sector are maturing and nearing success, with Ventracor a feature of this week's edition. Other companies such as Sirtex Medical have crossed the line, Starpharma continues to increase in appeal, and Cogstate has an important 12 months ahead.

The editors
Companies covered: CGS, SPL, SRX, VCR

	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 (from 4 May '07)	-10.4%
Cumulative Gain	**193%**
Av Annual Gain (6 yrs)	**26.8%**

Bioshares is published by Blake Industry & Market Analysis Pty Ltd. The company also provides market and company analysis of the Australian pharmaceutical and biotech industries for local and international funds management institutions, venture capital funds and other related industry groups. For further details contact David Blake (see details below).

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Ventracor....Success Now Within Reach

Ventracor (VCR: 62.5 cents) has trod a long and difficult road since the company first launched plans to develop its own mechanical heart pump in 1998. Having spent over $150 million since the company was formed, with the majority to fund the development of the VentrAssist device, the reality of having created a successful international medical device business is now within reach. *Bioshares* attended the company's AGM in Brisbane this week where talk of even payment of dividends to the company's patient shareholders was being entertained as an approaching issue for the company to consider.

Up to 270 implants this year

As of Tuesday this week, the company had implanted 158 of its left ventricular assist devices (LVADs) to patients with end stage heart failure. This financial year is likely to be a pivotal year for the company, the 'tipping point', as it expects to implant between 170 – 270 heart pumps, generating as estimated revenue stream of between $17 million – $27 million for the year working on a device sale price of $100,000.

It is a brave move by the company to be forecasting future sales of its devices. This is likely being driven by the confidence the company has in achieving the target range it has released, but also by the company's poorly performing share price, which has fallen by 50% this year.

One of the problems the company has is its large cash burn, generating a loss of $36 million last year, and the need to revisit the market on a regular basis to fund its development work. Our estimate is that this burn rate will fall during the course of this year although will still leave the company with a net loss of around $25 million at the end of this financial year with about $23 million in cash reserves.

To bring the company to a breakeven point, we estimate it will need to sell approximately 600 pumps a year. For the company to become highly successful it needs the LVAD market to break open and there are a number of factors in its favour that may stimulate this market demand.

US market driver

The US market is clearly vital for Ventracor. This is because the LVAD and the implant procedure are fully reimbursed by the healthcare system. There are approximately 2000 heart transplants conducted in the US each year and about 40% of those patients are implanted with an LVAD device.

However, that market is set for strong growth with the expected approval of the Heartmate II for bridge to transplant from Ventracor's competitor Thoratec. There are two categories of LVAD procedures: the bridge to transplant (BTT), which is a temporary implant for patients awaiting a heart transplant; and destination therapy (DT) as a permanent implant. The Heartmate II is a significant improvement upon existing approved LVADs in the US.

Cont'd over

And arguably the Ventracor device is an improvement on the Heartmate II device, being a third generation device.

Ventracor's heart pump is approved for sale in Europe and Australia and in the US it is about two years behind the Thoratec Heartmate II in being approved for bridge to transplant use.

The market for BTT recipients is not limited to the 2000 heart transplants conducted each year. Some patients are too ill to be considered for a heart transplant, but an LVAD has the potential to improve their health and make them viable for a heart transplant. Once reliable LVADs become available for BTT, the indication between BTT and destination therapy could become blurred as cardiologists become more comfortable with recommending LVAD use.

In 2006, Thoratec generated revenue of US$105 million from LVAD sales. With destination therapy use, the market may potentially increase to over US$500 million in coming years. Both Throratec and Ventracor are very well placed, being the two clear leaders in this market.

Ventracor is currently conducting a 140 patient BTT trial in the US, where payment for each device implanted is received and 11 patients have so far been enrolled. In the DT trial, five patients have been enrolled with an expected 120 from the 180 patients to be enrolled to receive a VentrAssist system. Devices used in all US trials generate full product income for Ventracor.

European market

In the last financial year, about 400 LVADs were sold into Europe in a market that has the capacity to increase 10-fold. Last year Ventracor sold 23 LVADs into Europe and so far this year has sold 16, gaining market share from competitors. Both Thoratec and Berlin Heart are existing competitors in this market. However, sales are restricted by the lack of reimbursement, with reimbursement currently in the UK, Germany and Scandinavia. Nevertheless, there is a push to see the products reimbursed in France, The Netherlands and Belgium, and Ventracor is behind the push to put on additional centers to conduct the LVAD implants. Ventracor has put trained people in13 centres in Europe to conduct the implant procedure since the device was approved there in December 2006.

Other markets

There are four centers in Australia that conduct the LVAD procedure. The devices are currently paid out of the hospital budget which has a set limit of LVAD implants they can conduct each year, estimated at around 40 in total. The company is currently in the process of gaining reimbursement for the device and procedure in Australia, where it would be covered by private health insurers if it is successful. There is also an intention to explore new opportunities in Honk Kong and India.

Future improvements

As the market grows for LVADs, more funds will go towards building next generation devices, which include improvements such as fully implantable systems and improved battery life. Infection remains an issue for recipients, with the site of the cable connection through the skin being the main cause, although the company says it is becoming better at reducing the incidence. Recent improvements in the device have included a detachable external cable, which previously has caused serious problems when caught by external objects, and a large reduction in the external back pack carried by the patient.

Summary

Ventracor is currently capitalized $188 million with an estimated $38 million in cash. The market for LVADs currently supports the development of the VentrAssist device, however it is the anticipated growth in this market that has the potential to turn Ventracor into a very successful medical device business. There are two leading players in this market, being the established Thoratec and the emerging Ventracor business, which will be very competitive against the market leader.

The Ventracor LVAD device appears to work very well and reliably, having been implanted now into almost 160 recipients. In previous trials it has shown to increase one year survival to 74% in end stage heart failure patient recipients, where 50% survival might be historically expected. Significantly, it has also been shown to improve some patients to a level where the device can be explanted once the natural heart has been unloaded and allowed to repair.

The competition from stem cell treatment is real, although may be another five to ten years away from being an established therapy, and may also be used in conjunction with LVADs to remove loading from the heart as the heart muscle regrows.

Ventracor is a well managed business that is moving into the final stage of building a profitable and successful international medical business. That the development of this program has been achieved in only nine years is an impressive effort. The share price weakness over the year provides an attractive investment option into this later stage medical device stock.

It is still not without risks, including the need to grow the current market for such devices, risk from the US regulatory approval process, the risk from competitors and the risk associated with the use and sale of such life support devices.

Bioshares recommendation: **Speculative Buy Class A**

Ventracor has been added to the Bioshares Model Portfolio at 62.5 cents

Bioshares

AusBiotech 2007 Conference Wrap – It's All Good!

The mood at the annual AusBiotech conference held in Brisbane this week was very buoyant. Over 1400 people attended with 87 international speakers presenting. The interest from major international pharmaceutical groups was high, with these companies looking to fill their underperforming development pipelines. And the message is that Australia is very much on the radar of international pharmaceutical companies and investment groups.

The international delegation to Brisbane included 12 business development people from Bristol-Myers Squibb (BMS), 12 international representatives from Pfizer, six from Roche, two from Merck Sharpe Dohme and there were representatives from Amgen and GlaxoSmithKline.

There was also a strong showing by Californian Venture Capital funds, with 13 angel investors making the trip over to Australia for the event. Feedback from local biotechs has been that partnering sessions were extremely valuable with a marked change in interest from potential pharmaceutical partners.

Why the change in heart from major pharmaceutical groups? One possible answer is that the success Australia is having in its later stage clinical programs is having an impact on overseas business development teams, prompting them to investigate what else might be of interest in Australia.

The escalating amount of funding flowing into the local sector and the increasing pool of international investors active here is also helping put Australia on the map. In 2007, close to $1 billion is expected to be raised by Australian biotechs, up from $534 in 2004.

Australia is now the sixth largest biotech region in the world. The trend being seen across the global biotech sector is that big pharmaceutical companies are partnering earlier. This is due to the reduced number of clinical stage partnering opportunities that are now available. Pharmaceutical companies have also acknowledged the need to look in less obvious places for partnering options, according to BMS, hence the increasing interest in Australia. Graham Brazier from BMS said that Australia is getting a really good track record and the excuse can no longer be made that Australia is too far away.

And he's right. The outlook in Australia is very good. Over the next four yeas we can expect up to 10 drugs potentially reach the market that are currently in, or planning, the final clinical trials before registering for approval. Even taking a conservative view that only 50% will succeed, then we should see at least five Australian developed drugs make it to market over the next four years, or one drug about every 10 months on average. And this excludes the solid progress being made by numerous Australian-listed medical device companies, including Sirtex Medical, Ventracor, Sunshine Heart, Universal Biosensors and CathRx to name a few.

Although the share prices of many Australian biotech stocks are underperforming at the current time, we are arguably approaching the golden age of Australian biotech. And it's worth noting the impact of the key investment banks such as ABN Amro Morgans, EG Capital, Lodge Partners and Wilson HTM are having in facilitating the necessary access to capital to bring these products to market and help the Australian life science firms compete on an equal footing with their international biotech competitors.

Personnel Changes

Several companies announced changes to their management line-ups this week. At the Institute of Drug Technology Australia AGM held this week, Chairman and Managing Director **Dr Graeme Blackman** announced that from January 1, 2008, the current General Manager Dr Robyn Elliot would take on the role of managing director. Dr Elliot has been with the company for twelve years. Dr Blackman will continue as chairman of the company.

This is a positive and significant move for IDT Australia as it will allow a fresh face to present the IDT investment argument and business proposition to the investment market.

Circadian Technologies announced that **Graeme Kaufman** had resigned as a director and would be leaving the firm towards the end of the year. It is understood that Kaufman will be leaving Circadian to become the Chief Investment Officer of a new $400 million biotech investment fund. This fund is being set up with the involvement of **Bob Moses**, the chairman of Antisense Therapeutics, Sylvan Scientific and TGR Biosciences, **Peter Burton**, a venture partner with 3am Capital and **Igor Gonda**, a former CEO of Acrux. Kaufman described the fund as being "interventionist" in nature, to invest in listed life science firms in Australian and the US.

The establishment of a new $400 million fund that will be focused on listed life science companies is very good news for the sector. Such a fund may address several weaknesses in the current way in which biotech companies obtain funding. Frequently the stock prices of well structured and well managed companies can be over-

Cont'd over

sold because of overall negative market conditions. With falling or sustained low share prices, such companies can face very difficult funding situations, and the presence of an active investor may improve share price stability. Secondly, an ‘interventionist’ fund is more likely to act quickly and directly to impose change when internal processes are unable to do so.

Bioshares

Starpharma Signs on Second Condom Manufacturer

Starpharma Holdings (SPL: 47 cents) has continued to progress the commercialisation of its dendrimer based Vivagel coating with the signing of a second condom manufacturer, SSL International, the owner of the Durex brand of condoms. SSL International holds 30% of the global condom market. The deal includes undisclosed milestone payments and co-development arrangements. A deal with another undisclosed condom maker was made in July this year.

The benefits of Vivagel when used as a condom coating stem from its contraceptive and microbicidal properties. Thus condom manufacturers can reinforce their products with new features and maintain a competitive position in a market estimated to be worth US$3.2 billion and growing at 4-5% per annum.

Starpharma’s approach to commercialising products based on dendrimer chemistry includes the development of multiple licensing opportunities across the life science research, pharmaceutical and industrial products areas. In time, the creation of multiple royalty income streams should see the generation of solid revenues for Starpharma. Starpharma is capitalised at $84 million.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

Sirtex Medical Shares Continue to Move

Shares in Sirtex Medical ($4.62) climbed 11% this week, on the back of the news flowing from the company’s AGM and the filing of the company’s latest quarterly cash flow statement. Cash receipts posted for the September quarter were $9.1 million, down from the previous quarter of $9.8 million, but up 50% from the September quarter 2006. It is likely that the northern hemisphere summer holiday period contributed to the slight dampening in sales, However, this growth rate is in line with the rate of revenue growth recorded for FY2007 of 45%

The company is continuing to support the marketing of its liver cancer treatment product Sir-Spheres through the management of clinical trials. The company is directly managing six trials and supporting another eight.

Expectations

Sirtex implied that generating strong bottom line profitability may not be a short term priority for the company, with the company emphasising that it is investigating how the Sir-Spheres product can be improved. It is continuing to work on its hypothermia technology and is investigating how to expand the use of Sir-Spheres into non-surgical applications, and finally develop a radio-protector technology licensed from the Peter MacCallum Cancer Centre in Melbourne.

An X-factor in the Sirtex investment story is if and when the company’s North American facility becomes operational. The utilisation of this facility could be the source of a huge lift in North American revenue as a much greater treatment window becomes available to interventional radiologists in North America. No mention of the Massachusetts facility was made at the AGM. The resolution of the current litigation with the University of Western Australia, which is expected this year, may also be short term driver for the stock. Sirtex Medical is capitalised at $258 million.

Bioshares recommendation: **Buy**

Bioshares

Cogstate – An Important Year Ahead

Cognitive testing products company Cogstate (CGS: 14 cents) grew sales in the September quarter with the company generating a revenue of $736,000 for the first quarter of this financial year. This brings the trailing 12 months revenue to $2.7 million, which is still short of the estimated $4.5 million in sales the company needs to break even.

A positive sign for the company is that the business is showing a more consistent growth trend with an even stronger second quarter expected this financial year. Last year was disappointing for the company with clinical trials sales revenue increasing by only 30% over FY2006. The company now has five major pharmaceutical companies as clients, with four of those providing repeat business for Cogstate. The company’s quote book has never been stronger with pharmaceutical companies now approaching Cogstate to bid for work. Sales for the first six months of this financial year should approach $2 million.

To its advantage, Cogstate is not looking to build new markets for its clinical trials service/product, but is seeking to gain market share from competitors and to benefit from the increasing number of CNS drug trials being conducted. Its main competitor, Cognitive Drug Research in the UK, has shown that a good profitable business can be built around the service of cognitive testing for clinical trials.

Cont’d over

Cogstate has expanded its team significantly over the last 18 months, now employing 24 people on a full or part time basis. It will look to shortly install a marketing person in the UK to expand its work into the European market.

The longer Cogstate remains in this market, the more established and better known to customers it should be. Accordingly, building sales should become easier, which is starting to occur for the company, compared with two years ago.

FY2008 a crucial year for Cogstate

This will be a crucial financial year period for Cogstate, when it needs to get its business right, otherwise it will be a long and hard road ahead for the company. Costs will need to be contained to ensure profitability is achieved in FY2009. If the company can generate sales of $4 million this financial year, then $6 million of revenue should be a realistic objective FY2009, which would generate an estimated $0.7 million in net profit after tax.

An arguable sales multiple valuation for the Cogstate business is three times sales, which based on the trailing 12 month revenue equates to a valuation of $8.1 million, or 16 cents a share. If the company can begin to deliver consistent quarterly sales revenue in excess of $1 million, then an uplift in the company share price can be expected. Judging by the company's positive assessment following recent results, the first such quarter may be forthcoming. Cogstate is currently capitalised at $7 million with $1.5 million cash at the end of September.

Bioshares recommendation: **Speculative Buy Class B**

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Bioshares Model Portfolio (26 October 2007)

Company	Price (current)	Price added to portfolio
Acrux	$1.35	$0.83
Alchemia	$0.73	$0.67
Biota Holdings	$1.48	$1.55
Circadian Technologies	$1.26	$1.45
Clinuvel Pharmaceuticals	$0.49	$0.66
Cytopia	$0.46	$0.46
Chemgenex Pharma.	$1.09	$0.38
Optiscan Imaging	$0.39	$0.35
Peplin Ltd Inc	$0.90	$0.83
Peptech	$1.14	$1.31
Pharmaxis	$4.10	$3.15
Phylogica	$0.23	$0.42
Probiotec	$1.26	$1.12
Progen Pharmaceuticals	$2.77	$3.52
Sirtex Medical	$4.62	$3.90
Starpharma Holdings	$0.47	$0.37
Sunshine Heart	$0.16	$0.19
Tissue Therapies	$0.43	$0.58
Universal Biosensors	$1.18	$1.23
Ventracor	$0.63	$0.63

Portfolio Changes – 26 Oct 2007

IN:

Ventracor, 62.5 cents, see article on page 1.

OUT:

No changes

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

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