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In this edition...
Just two companies are the focus of our attention this week. Ventracor, one of the most resilient and dedicated device companies around continues its march towards revenues. The dollars should grow as clinical trials of the VentrAssist device in the US incur greater patient numbers. Ventracor should also benefit from some key changes in the LVAD market in the US.

Our second company is Patrys, an antibody company that has deliberately established a base in Australia. This may be one of the hottest listings of the year, and it is well worth the time to find out what they do and why they are here.

The editors
Companies covered: VCR, Patrys 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)	70.0%
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)	5.4%
Cumulative Gain	**244%**
Av Annual Gain (6 yrs)	**26.8%**

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Bioshares

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

Ventracor Gets Sales Traction Through Major US Studies

The market for Left Ventricular Assist Devices (LVADs) may be about to step up to a new level over the next 12 months. LVADs are small mechanical heart pumps that are implanted into the body largely to assist with pumping blood from the left ventricle throughout the body (the right ventricle pumps blood through the vasculature of the lungs). Two Australian companies are developing competitive products in this space with a third company working on an alternative approach.

Ventracor (VCR: 77 cents) and **Heartware** are developing LVADs, both third generation devices (centrifugal pumps) with Ventracor around two years ahead of Heartware and Heartware's device is approximately half the weight of the Ventracor device. **Sunshine Heart** is developing an implantable sleeve that wraps around the aorta and provides a different form of support for circulatory function.

Existing market description

There is an existing market for LVADs which is largely concentrated in the US (estimated 80%) worth roughly US$200 million a year. In the US the device and the implant procedure is fully reimbursable. About 2000 of these devices are implanted each year. There are several devices approved for use in Europe but in the major market of the US, only one such device is approved for what is termed destination therapy, the **Thoratec Corporation** LVAD, HeartMate XVE. Destination therapy (DT) implies a permanent implant, as opposed to Bridge-to-Transplant (BTT), which as the term suggests is only for use until a heart becomes available for a heart transplant. There is only one other company that has an LVAD approved in the US for BTT.

Thoratec is capitalised at US$1 billion with 60% of its revenue generated form the sales of LVADs. LVAD sales in 2006 totalled US$105 million and this year sales are expected to exceed US$140 million. The company produced a net loss from operations (US$1.6 million) in 2006 compared to a US$17.9 million income from operations in 2005. The relevance of these details is that a reasonable market exists for LVADs and that a profitable business can be achieved, at least by 2005 numbers.

Where to from now for LVADs?

In understanding the potential value from developing LVADs, it's necessary to predict where the LVAD market is heading. Most of the sales of LVADs have been for use in BTT, because the existing approved LVADs are just not reliable enough. The HeartMate XVE approved for use in the US for DT and BTT has a life-span of generally less than two years. Cardiologists are not referring their patients for DT because of the reliability issues.

The dynamics of this industry may be about to change. Thoratec has completed its US BTT study with its second generation device, the HeartMate II. The device is an axial

Cont'd over

flow, high speed device (6000 – 15000 rpm) that is slightly heavier than the Ventracor third generation centrifugal LVAD which has a speed of between 1800 – 3000 rpm.

Next year, we may start to see the US market for LVADs break open when what looks to be a reliable product, the HeartMate II, being released. The FDA has requested additional data from Thoratec to support the submission for approval of HeartMate II for BTT. There may be some delay, however, the data looks reasonably good for HeartMate II, with 75% of patients reaching the primary endpoint, being survival at 180 days from implant or patients being successfully transplanted with a donated heart within this time period.

Some of the issues Thoratec is resolving with the FDA is how to count patients who voluntarily removed themselves from the transplant list because their heart function improved. Also there is insufficient data on implants in adolescents and Thoratec may include data from earlier trials to gain approval.

Potential blurring between BTT and DT

According to the Principal Investigator of the Thoratec trial, physicians are looking favorably towards blurring the distinction between BTT and DT. This is a decidedly important development for this industry. Thoratec's DT trial with the HeartMate II completed enrolment last month in 200 patients and the trial will require a two-year follow-up period. While FDA approval for DT may be up to three years away, if a reliable LVAD becomes available on the market, then it may begin to be used for not only BTT but usage may start to crossover to DT. If this occurs, we could see the LVAD market increase from the current US$200 million to in excess of US$500 million over the coming years.

Market constraints

Higher take-up of LVADs in the US is constrained by the lack of approved, reliable devices. Another constraint however is the added healthcare cost associated with the implant of these devices. A report from the US investment bank Rodman & Renshaw, states that because of morbidity issues, the cost of LVADs increases the cost from US$135,000 to US$900,000 because of extended hospital stays. Infection remains the major issue with LVAD implants, with approximately 30% of patients affected.

Ventracor's CE Mark trial in 33 patients showed that after 30 days from implant, 18% of patients experienced local infections and 12% of suffered a systemic infection.

Ventracor

Although the clear leader in the LVAD market is Thoratec, a US analyst report in December last year cites Ventracor as the most advanced competitor to Thoratec. Ventracor is about two years behind Thoratec's HeartMate II. Its European trial in 33 patients showed that 82% of patients reached the endpoint at 154 days post implant either through transplant (39%) or by staying on the device (42%), which is competitive with the HeartMate II (75% at 180 days).

Ventracor has now implanted over 120 patients in total. Of the first 100 patients, as reported in April this year, the longest survival on the Ventracor VentrAssist was over 2.5 years, with mean support of six months and 36 patients continuing to be supported by their device. Another way to view the data was that 32% survived longer than six months, 16% longer than one year, and 2% longer than two years.

Trial design structure

The VentrAssist device is selling in Europe and is awaiting TGA approval in Australia (although the device is available under the Special Access Scheme whereby the hospital must pay for the device). Ventracor has started its BTT trial in the US. A total of 140 patients will be involved which will be a single arm study. The trial goal is to achieve 75% +/- 10% of patients to survive to 180 days either on the device or transplanted with a donor heart, which will be seen as successful by the FDA. Ventracor will be reimbursed for each device implanted (about $100,000).

The DT therapy trial is due to begin shortly. It will involve up to 180 patients with end stage heart failure, in a module format. For the first module, two thirds will receive the VentrAssist and one third optimal medical management. The second module will involve 45 patients requiring an LVAD within 48 hours, with two thirds to receive the VentrAssist and one third the HeartMate XVE. The primary outcome of both modules is stroke-free survival.

BRACE study

Ventracor is conducting a post market study in the UK with VentrAssist. The study will follow up to 100 patients implanted with the Ventracor device and will provide information including cost effectiveness data to support the marketing of the device in Europe and the US. This study has the potential to increase awareness of the device with cardiologists.

Positive changes in LVAD hospital requirements

Up to 40 hospitals will be involved in the two US trials and we do not expect there to be difficulty in recruiting patients. In other positive developments, the Centers for Medicare and Medicaid Services (CMMS) in the US has modified its criteria for hospitals implanting LVADs. Hospitals conducting LVAD implants now no longer need to be approved transplant facilities, and the number of LVADs that need to be implanted by hospitals over three years to be eligible has decreased from 15 to 10. This will significantly increase the number of centres that can perform LVAD procedures and is another factor in removing barriers to more regular use of these devices.

Implants (and sales) accelerating for Ventracor

Ventracor is now implanting 10 devices a month, generating revenue of around $1 million a month. We estimate that in the order of $30 million in revenue will be generated over the next two years from the US trials alone with additional sales expected in Europe and potentially Australia. In Europe, Ventracor is using a combination of direct sales and distributors.

Cont'd on page 5

IPO Profile – Patrys Ltd

Patrys was formed as an Australian company in 2006. While this represents a recent start date for Patrys as an Australian entity, the technologies within the company emanate from several companies formed in earlier years, and from research commenced as far back as 1992. Patrys' formation goes back to 2004, when the founders of two natural antibody companies, **Acceptys, Inc** and **OncoMab Gmbh**, and Dr Peter Vollmers and others from the **University of Wurzburg** sought to combine their respective assets and place them in a new entity that could access funds and manage clinical development programs in a mutually acceptable territory.

Application of funds

Patrys is intending to raise $25 million. It indicative capitalisation base on its offer price of 40 cents per share is $60 million. The total number of shares on issue at the close of the offer will be 150.8 million. Patrys intends to allocate $23 million to manufacturing, pre-clinical and clinical development over a 30 month period ending October 2009. Another $2.8 million will go towards an investment in a related company, Acceptys, to obtain a 28% interest, and $3.2 million will be applied to working capital.

Natural antibodies

Patrys is developing natural human antibodies to treat various cancers. Antibodies are large naturally occurring proteins involved in immune system surveillance. They recognise and bind to antigens. Natural antibodies differ from monoclonal antibodies (mAbs). Monoclonal antibodies are antibodies produced from a single B lymphocyte cell or engineered cells such as hybridomas.

There are four main types of antibodies developed in the context of a search for suitable human therapeutics. These are respectively, murine (from a mouse), chimaeric (half-mouse, half-human), humanised (mostly human with just a few mouse components remaining) and human (containing no mouse protein at all).

Human antibodies can be generated through a technique called phage-display (as developed by **Cambridge Antibody Technologies** and **Morphosys**), or from human B lymphocyte cells and human hybridomas, which is the approach adopted Patrys.

What is a hybridoma?

The concept of a hybridoma is an important feature of antibody technologies. Antibodies are produced by B lymphocyte cells. However, these cells are short lived when taken outside the body. This problem was overcome when the B cell was engineered or fused with a cell capable of regenerating indefinitely and therefore capable of continually producing antibodies of choice. The 'immortalised' cell line chosen for this task was a cancer cell known as a myeloma cell.

Antibodies and cancer

Antibodies have been exploited as therapeutics for their capability to recognise in a highly selective manner other proteins (antigens) involved with diseases, eg a cell surface protein that is found only on certain cancer cells, and then instigating a biological response. More than 20 antibodies have been approved for therapeutic purposes and a dozen have been approved specifically for cancer indications. According to *Nature Reviews Drug Discovery*, 206 unique antibodies against 76 targets were studied as cancer treatments in clinical trials under commercial company sponsorship from 1980 to 2005. Currently 85 antibodies are in clinical development as cancer therapeutics around the world, excluding antibodies that have already been approved for one or more indication.

Patrys has developed its own proprietary human hybridomas, from which it can produce fully human antibodies. It has discovered these 'natural' antibodies by investigating samples from spleen and lymph nodes taken from cancer patients. Spleens and lymph nodes are a rich source of antibody producing B cells.

Advantage of natural human antibodies

An advantage provided by natural human antibodies over antibodies generated by other methods is that they should be far less likely to generate an immunological response. Chimaeric and humanised antibodies are decorated with non-human carbohydrates, which are treated as 'foreign' by the human body, which then stimulates an immune response to eliminate them and negating the effect or benefit of the therapeutic antibody. The degree of response varies, but it is a recurring issue. For antibodies produced in non-human cell systems, once again the decoration with non-human carbohydrates occurs, and the potential for an immune response exists.

Development Pipeline

Patrys has three antibody candidates in development. These are PAT-LM1 for lung cancer, PAT-SM6 for pancreatic cancer and PAT-CM1 for colon cancer. It plans to progress its two leads, PAT-LM1 and PAT-SM6 into clinical trials towards the end of 2008, with partnering a further objective. The company states that these two lead antibodies bind to over 90% of patient tumours, in screenings obtained from 400 patients.

The company also intends to evaluate a number of other antibodies, and antibodies sourced from its 'back-up' portfolio in pre-clinical studies, with the intention of also progressing such leads into further development. The company has a portfolio of 256 antibodies that may yield more candidates for the drug development pathway.

Strengths

Unique targets

The Patrys natural antibody candidates have been generated against unique cancer targets. The company's discovery philosophy has been to identify antibodies associated with a disease state first and then discover the relevant target. This is important for two reasons. The first is that the antibody should only be associated with the disease state, and be irrelevant to healthy tissues. The second is that company's prospect of uncovering novel targets is higher. These novel targets could potentially be patented by Patrys and offer the benefit of legally blocking (through patents) antibodies developed by other companies. A number of patents filed by Patrys that cover antibodies also cover target antigens.

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Collaborations and Agreements

Patrys has several inherited collaborations and licensing arrangements. **AstraZeneca**, through its acquisition of **Cambridge Antibody Technologies (CAT)** is developing the antibody PAT-SC1, as a treatment for gastric cancer. This antibody which was originally licensed to **H3 Pharma**, which was acquired by **Debiovision**, which in turn licensed the antibody to CAT.

Oncomab GMBH also licensed another antibody, PAT-PA1, to Debiovision.

Patrys also has a collaboration with **Takeda** of Japan, which it commenced in March 2007. The deal allows Takeda to evaluate a number of antibodies from the Patrys portfolio, and select up to five for further development. The arrangement excludes the current Patrys lead candidates. Takeda has made an investment in Patrys of US$750,000 that converts into shares at the completion of the offer, and will invest a further US$750,000 at the offer price, to give it a 1.6% stake in Patrys.

A lesser royalty stack

One attractive feature with Patrys' natural human antibody technologies is that the technology is not encumbered by multiple in-license obligations, otherwise known as the 'royalty stack'. At this stage the company is potentially required to pay only low single digit royalties to original owners (Dr Vollmers, Oncomab and the University of Wurzburg) in respect of certain assigned assets

Board and management

The CEO of Patrys is Daniel Devine, an executive with a legal and business development background, including time spent in the latter capacity at Pfizer. Devine is the founder of Patrys and also of Acceptys, an associated company which is developing infectious disease applications of the Patrys' technologies and in which Patrys is set to take a 28% stake (fully diluted) on successful completion of the IPO.

The chairman the Patrys board is John Read, a director and chairman of several other Australian private and public companies. Other board members include Michael Stork, the managing director of **PNK Holdings**, an original investor in Acceptys and Patrys, and Dr Alan Robertson, the CEO of **Pharmaxis**. The presence on the board of a CEO of a leading Australia biotech company as a non-executive director is noteworthy. Australian biotech CEOs are emerging as solid candidates to meet the requirement to populate biotech boards with people experienced in developing internationally focused biotech companies. Alan Robertson's particular experiences in fund raising and managing clinical trials at Pharmaxis may prove of value in guiding the activities of Patrys going forward.

Weaknesses

Manufacturing

An important issue that investors need consider with Patrys is that of manufacturing. Of a number of higher order risks including clinical development risks, this is perhaps the major risk associated with an investment in Patrys. According to the Patrys prospectus, the company's human hybridoma cells have not been deployed in large scale manufacturing systems. One of the reasons natural human antibodies, which have been recognised as potentially useful for many years, have not been commercially exploited is because commercially viable production methods have not been developed.

The Patrys prospectus states that the company has been successful in growing and expanding human hybridomas that generate its lead antibodies in scalable systems provided by third parties, in sufficient quantities to support development. However, the company must be able to satisfy regulators that such manufacturing methods produce goods that meet safety standards, such as those relating to batch consistency and purity, and are performed to Good Manufacturing Practice (GMP) standards. The company has commenced GMP process development for its two lead antibodies.

The company claims that its human hybridoma systems deliver antibody production levels that are substantially higher than levels reported in known alternative hybridoma systems. However manufacturing development not only includes meeting purity and yield issues, but also cost. If the company is not able through third party manufacturers to make its antibody products to an acceptable cost-of-goods margin, then the prospects for the company will be significantly diminished.

Patents and ownership

An outstanding issue for Patrys is that company has no granted patents in respect of antibodies (PAT-LM1, PAT-CM1, PAT-SM6) it has selected for development. The patent applications covering these antibodies also describe methods for isolating and producing the antibodies. It also has no granted patents covering a human hybridoma cell line, PAT-TRAB4. Until the clarity of the exclusive right to exploit an invention (as is provided by patents) is confirmed, then a not insignificant risk is attached to an investment in Patrys. It could be several years at least before if/when these patents are granted in key jurisdictions, such as the USA and Europe

Lack of 'pedigree' investors

In many instances the presence of a specialist biotech investor, including but not limited to venture capitalists, is a sign to investors that the investment proposition has been previously assessed with a reasonable degree of acumen, and constructively supported in its development to date. It would appear that no particular specialist biotech investor of note has been associated with Patrys or its predecessor companies to date.

Limits to antibody treatments

Antibodies are very large molecules, which means administration by injection is the most suitable route of delivery. This limits the development of antibody-based therapies to where injections have a higher degree of acceptance, such as cancer. A competitive tension is likely to continue between orally delivered medicines and injectable medicines that have very specific targeting capabilities such as antibodies.

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Ventracor - from page 2

Summary

Ventracor is moving to an important inflexion point for the commercialisation of its technology. A profitable market currently exists for LVADs and there is a positive swing in events that is likely to see a wider adoption of LVADs into the far larger market of destination therapy, which is estimated to be in excess of 25,000 implants a year.

However there are constraints, including supporting infrastructure and the associated healthcare costs that will prevent this market potential being fully satisfied. Infection remains an issue, although patient management should continue to improve. We believe there is the potential, however, for the existing market (US$200 million a year) to see up to a three-fold increase over the next five years as more reliable and effective LVADs come on to the market. Being in second place with a competitive device is an attractive position to be for Ventracor as its sales begin to accelerate and its products move through registration trials in the US.

Ventracor is capitalised at $233 million with an estimated $38 million in cash following the recent $21 million private placement.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares Model Portfolio (22 June 2007)		
Company	**Price (current)**	**Price added to portfolio**
Acrux	$1.58	$0.83
Alchemia	$0.95	$0.67
Biodiem	$0.28	$0.29
Biota Holdings	$1.78	$1.55
Circadian Technologies	$1.34	$1.45
Cytopia	$0.66	$0.46
Chemgenex Pharma.	$1.08	$0.38
Optiscan Imaging	$0.46	$0.35
Peplin	$0.85	$0.83
Peptech	$1.45	$1.31
Phylogica	$0.36	$0.42
Probiotec	$1.30	$1.12
Starpharma Holdings	$0.40	$0.37
Sunshine Heart	$0.20	$0.19
Tissue Therapies	$0.62	$0.58
Universal Biosensors	$1.53	$1.23

Patrys - from page 4

Another issue with antibody therapies is cost. A number of antibody therapies that have gained market acceptance and commercial success are relatively expensive, although it would appear the benefits obtained from these treatments has justified higher relative costs. A contemporary issue for all antibody therapies is pricing, and as more antibody therapies emerge, the challenge of pricing antibody therapies in a way that balances investment considerations with healthcare payor concerns is likely to increase in difficulty.

Commentary

The Patrys offering is interesting for several reasons. It is not the first time assets, know-how and management expertise from around the globe have been bundled into an Australian entity and floated on the ASX. However, on this occasion, Patrys has chosen to locate its headquarters in an Australian city (Melbourne) and intends to undertake development programs in conjunction with Australian medical institutions.

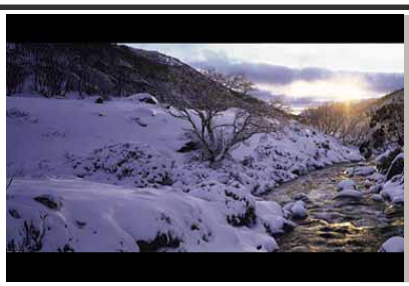
The Patrys offering is also well timed given the heightened interest globally in antibody and related technology companies, such as antibody fragment companies or companies developing novel scaffold and binding technologies, and companies that offer proprietary protein optimisation and humanisation technologies. The demand for these technologies and companies is evidenced by a recent string of acquisitions in the area, including **AstraZeneca**'s acquisition of **Cambridge Antibody Technologies** last year for US$1.3 billion, **Amgen**'s acquisition of **Abgenix** for US$2.6 billion and **GlaxoSmithKline**'s acquisition of **Domantis** for US$454 million. Acquisitions in the area have usually been preceded by licensing and collaboration arrangements.

In order to maintain profitability, large pharmaceutical firms have a requirement to maintain a portfolio of medicines with long patent life that offer new or improved benefits to patients. The various antibody technologies now developed have proven to be a commercially viable source of medicines that meet these criteria across a range of diseases. This is an underlying and very significant driver of demand in the antibody arena, and an important consideration to bear in mind when studying the Patrys investment proposition.

Key Dates of the Offer

Opening date	June 18, 2007
Closing date	July 6, 2007
Expected date of quotation	July 20, 2007

The offer is fully underwritten by Lodge Corporate Services Pty Ltd. Investors are required to read the prospectus, a copy of which can be downloaded from www.patrys.com .



Bioshares

Thredbo Biotech Summit

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We are delighted to announce that the Special Dinner Speaker for the Thredbo Biotech Summit will be **Tony Featherstone**, the former editor of BRW Magazine. Tony is one of the country's leading business editors and prior to BRW, was editor of Shares, Personal Investor, Asset and CFO magazines and Shares Weekly. He has recently been appointed Fairfax Business Media online editor.

The third annual Bioshares Thredbo Biotech Summit is only four weeks away. Heavy snow falls have covered Thredbo this week and with more forecast, it will be an ideal venue for the country's leading biotech managers and investors to come together to discuss current issues and themes affecting the local and international biotech sector. We hope you can join us!

Thredbo Biotech Summit 2007 – Current Speaker & Facilitator List

Bill Kridel, Managing Director, Ferghana Partners Group, New York
Joseph Balagot, Merriman Curham Ford, San Francisco
Michael Aldridge, CEO, Peplin Ltd
Allen Bollands, CEO Genera Biosystems
Ian Brown, CordLife Ltd
John Chiplin, CEO, Peptech Ltd
Peter Cook, CEO, Biota Holdings Ltd
Peter Devine, Uniseed
Professor Michael Gilding, Swinburne Unversity of Technology
Carrie Hillyard, Partner, CM Capital
Mike Hirshorn, Director, Kestrel Capital
Cliff Holloway, Peptech Ltd
Justus Homburg, CEO, Progen Pharmaceuticals
Alan Liddle, CEO, PacMab Ltd
Malcolm McComas, Chairman, Pharmaxis & Sunshine Heart
Andrew Macdonald, CEO, Cytopia Ltd
Peter Mountford, CEO, Stem Cell Sciences Plc
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http://www.bioshares.com.au/thredbo2007.htm
If you haven't booked your accommodation yet, we suggest you do it right away. If you require assistance, then please contact us at *info@bioshares.com.au*

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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