ISSN 1443-850X

In this edition...
Our lead analysis in this edition focuses not on biotech companies, but the investment firms that raise money for them. Our survey for 2007 shows a new leader has emerged in terms of investment performance. Positive newsflow continues from the biotech sector, with Biota recording a half year profit of $5.5 million and announcing a share buy back, Heathlinx gains independent validation of its Ovplex diagnostic in early stage ovarian cancer, and Ventracor has thrown down the gauntlet to its competitors.
In another instalment in our Biotech Management series, Peter Bradley discusses risk mitigation. We also make record of Leon Serry's address to the Melbourne Life Sciences Lunch Club, prior to his retirement on March 1.
The editors
Companies covered: BTA, HTX, 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)	-32%
Cumulative Gain	**121%**
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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Individual Subscriptions (48 issues/year)
$320 (Inc.GST)
Edition Number 252 (22 February 2008)
ISSN 1443-850X

Bioshares

22 February 2008
Edition 252

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

Stockbroker & Investment Bank Performance 2007

In what has now become a regular annual feature in *Bioshares*, we measure the performance of stockbrokers and investment banks active in the life sciences space in Australia. There are now at least 10 investment groups that have become active in the biotech sector with eight of those employing at least one or more specialised biotech analyst to assess the small to medium cap listed Australian life science companies.

Measuring the performance of bankers and brokers can be a useful task for investors. The underlying indicator we are seeking to measure is that if investors participate in capital raisings, either through an IPO or a follow-on placement or rights issue, what type of return have these investments generated for the investor in the subsequent period.

To calculate the performance summarised in the table below, we look at funds raised through these financial brokers in the previous year (2006) to the year when the performance is judged (2007) where funds have been raised through follow-on placements and initial public offerings in 2006. We also considered the performance of these groups where funds were raised from IPOs in 2007 where they were the lead underwriters or sponsoring broker. The broker performance is judged only where more than two fund raisings have been conducted by that group over the relevant period.

2007 Results

In what was a difficult year for the biotech sector, the 'House of Lodge' as it has become known at *Bioshares*, or more officially Lodge Corporate Services, generated an outstanding performance in 2007. The average gain from its portfolio of companies for which it has raised funds was 32% The result was excellent for a number of reasons. As mentioned it was a difficult year in the sector with the next best performing investment house being Wilson HTM with an average 7.2% gain for the year.

Cont'd over

Performance of Biotech (life science) Investment Banks and Stockbrokers in 2007

Supporting Broker/Investment Bank	Av. Gain/loss over CY2007
Lodge Corporate Services	**32%**
Wilson HTM	7.2%
Tricom Equities	7.0%
Intersuisse Corporate	0%
ABN AMRO Morgans	-2%
BBY	-24%
eG Capital	-25%
Taylor Collison	-37%
Bell Potter Securities	-42%
Tolhurst Noall	-45%

Performance of Biotech Investment Managers 2007

Company	**Investment manager**	Gain/loss in 2007
Avexa	ABN Amro Morgans	80%
Chemgenex Pharm.	ABN Amro Morgans	75%
Metabolic Pharmaceuticals	ABN Amro Morgans	-95%
Ventracor	ABN Amro Morgans	-45%
Impedimed	ABN Amro Morgans	10%
Avastra	ABN Amro Morgans	22%
Genepharm Australasia	ABN Amro Morgans	-65%
Peplin	ABN Amro Morgans	0%
Portland Orthopaedics	Axis Financial Group	-67%
Viralytics	Axis Financial Group	-44%
Colltech	BBY	-64%
Phosphagenics	BBY	-29%
Avantogen	BBY	20%
IMI Medical	Bell Potter Securities	20%
Stem Cell Sciences	Bell Potter Securities	-42%
Clinical Cell Culture	Bell Potter Securities	-77%
Neuren Pharmaceuticals	Bell Potter Securities	-55%
Virax Holdings	Bell Potter Securities	-56%
Heartware	eG Capital	-18%
Life Therapeutics	eG Capital	-79%
Progen	eG Capital	-57%
ASDM	eG Capital	53%
Agenix	Intersuisse Corporate	26%
Sunshine Heart Inc	Intersuisse Corporate	-39%
Anadis	Intersuisse Corporate	-66%
Bionomics	Intersuisse Corporate	79%
Antisense Therapeutics	Lodge Corporate Services	5%
Evogenix*	Lodge Corporate Services	132%
Mesoblast	Lodge Corporate Services	-30%
Patrys	Lodge Corporate Services	19%
Biosignal	Taylor Collison	6%
Cogstate	Taylor Collison	-41%
Neuren Pharmaceuticals	Taylor Collison	-55%
Prima Biomed	Taylor Collison	-58%
Clinuvel Pharmaceuticals	Tolhurst Noall	-52%
Portland Orthopaedics	Tolhurst Noall	-67%
Halcygen Pharmaceuticals	Tolhurst Noall	-15%
Brain Resource Company	Tricom Equities	70%
Virax	Tricom Equities	-56%
Avexa	Wilson HTM	80%
Heartware	Wilson HTM	-18%
Peplin	Wilson HTM	0%
Hexima	Wilson HTM	-12%
Sunshine Heart Inc	Wilson HTM	-39%
Universal Biosensors	Wilson HTM	32%

* Calculation based on EVX share value when merger with AAH effected (79 cents)

Also impressive is that over the last four years that this survey has been conducted, Lodge has finished in the top two places, coming second to Wilson HTM in the previous two years. The result from the runner-up, Wilson HTM, has also been solid, finishing in the top two positions in the last three years.

Lodge and its investor base will have been please that a company it floated in 2005, Evogenix, was acquired by Arana Therapeutics last year at a large premium to the IPO price of 25 cents a share (at the date of completion of the transaction, the equivalent value of Evogenix shares was 79 cents). Lodge also successfully listed another antibody company last year, Patrys, raising $25 million. The stock finished up 19% for the year.

Lodge has ratched up a gear last year when it put on a dedicated biotech analyst, Matthijs Smith, who has a biotech and investment background.

Best Stockbroker/Investment Bank Performances

Supporting Broker/Investment Bank	Year	Performance
Lodge Corporate Services	2007	32%
Wilson HTM	2006	76%
Wilson HTM	2005	28%
Lodge Corporate Services	2004	87%

Ventracor – Accelerates the development of a fully implantable LVAD

Ventracor (VCR; 45 cents) has thrown down the gauntlet to its competitors in the LVAD (Left Ventricular Assist Device) market this week surprising investors and other LVAD players, announcing it was accelerating the development of a fully implantable LVAD heart pump system.

The company also announced it had signed on a team of implantable device R&D team that was previously at St Jude Medical. The team will stay based in New Jersey although will be integrated with the Australian R&D team.

The most surprising aspect to move by Ventracor is that the company expects the fully implantable system to be introduced into the current Destination Therapy trial in the US 'ASAP'. The company expects that the US approval for its DT device will be a fully implantable system!

The Ventracor LVAD, called the VentrAssist, is approved for use in Europe and in Australia (it can be used for both Bridge-To-Transplant and as Destination Therapy) and is currently in a BTT and a DT trial in the US.

The list price for the device in the US is US$75,000. The company is reimbursed at full price for any devices used in the US trials and is currently selling devices into Australia and Europe. Sales revenue for the first half of this financial year were $6.2 million (up from $1.1 million for the previous corresponding period) and also importantly the net loss decreased, by 17%, to $14.9 million. For the first time the company has started down the path towards recording a positive income.

In Europe, the company increased the number of implants to 22 (from six for the previous corresponding period) and is working on expanding the distribution networks in that region. New distributors have been appointed in Greece and Italy, additional hospitals have adopted use of its device in Germany, and the company is working on reimbursement of the device in France and Belgium.

The BTT trial in the US is on track, with 38 of the 140 patients enrolled and enrolment expected to be completed this calendar year. Approval in the US for BTT is anticipated in two and a half years time in late 2010.

The DT trial in the US is running a behind schedule with surgeons wanting to gain further experience with the device in BTT trials prior to using it in DT trials. DT enrolment is expected to accelerate in this half year. To date 15 patients (from 225) have been enrolled.

To be successful in the LVAD market, companies need to be leading the pack on the technology front. The surprise move by Ventracor to accelerate its fully implantable system is another sign that the company is aware of the competitive edge that's required to be successful in this sector.

Bioshares Recommendation: **Speculative Buy Class A**

Bioshares

Biota Holdings – Announces Share Buy Back

Biota Holding (BTA: $1.28) reported its half year results for the period ending December 2007 this week, posting a profit of $5.5 million on the back of revenues of $30.4 million. Relenza royalties were $16.5 million, a 30% increase from the previous corresponding period (PCP). On a calendar year basis (ie CY2007), Relenza royalties increased 153% to $43.6 million.

The company expended $8.5 million on litigation, up from $3.4 million PCP, and expects to spend in the order of $15-$16 million in FY2008. To date, Biota has spent $27 million in legal costs since it commenced litigation against **GlaxoSmithKline** in 2005.

The company also announced a share buy back to acquire up to 5% of issued stock. Buy backs are typically a means by which companies signal to the market the belief that they are undervalued and are confident of the company's asset quality and strategic direction.

– Cont'd on page 7

Biotech History

Leon Serry's Address to the Melbourne Life Sciences Lunch Club

Leon Serry, the Managing Director of Circadian Technologies is retiring as of March 1, 2008. He will continue in a consulting role with the company but also expects to undertake various tasks on behalf of the biotech sector. The new Managing Director will be Robert Klupacs, who commenced working with Circadian as Manager, Strategic Development, in August 2005.

Serry founded Circadian 24 years ago and listed the company on the ASX's second board in March 1985. In a lunchtime address to the Melbourne Life Sciences Lunch Club on Friday February 22, 2008, Serry told the group that after 24 years of commencing work each day at 8.30 AM and finishing at 6 PM, he was "sad to be leaving" but needed some flexibility in his life to pursue other goals.

Serry recalled the time from when he conceived of establishing Circadian in the mid 1980s following reading a story in *Time* magazine on the newly emerging interferon drugs. He commented on several decades worth of biotech experience, including the company's early years with melatonin and the circadian rhythms project, the circumstances in which it sued **Eli Lilly and Co** and received a $5 million payment, and the company's particular approach to commercialising medical inventions.

However, Serry also commented on several challenges before the sector, arguing that "we can never have an industry in Australia until we get the money to fund Phase III trials". Serry believes that tax concessions for Phase III trials will provide a critical financial boost to the sector. Serry indicated that although he is stepping down from the MD role at Circadian, he will continue to play an active role on behalf of the Australian biotech sector, as an advocate and ambassador for a sector he is clearly passionate about.

He also said that despite the introduction of the ASX Code of Best Practice for Reporting by Life Science Companies, we continue to have a weakness in the area of clinical trial reporting and that much stricter clinical trials reporting guidelines would definitely benefit the sector. Consolidation was another industry issue raised by Serry, who expects to see a lot of consolidation occur, despite "the egos that get in the way".

The Circadian business model

Serry described the Circadian business model, which in Circadian parlance is called the Biocreator model, as an approach that has entailed early funding and early input. But Serry said "when we get a project that is really good, we spin it off." This has resulted in the listing of **Optiscan Imaging** , **Metabolic Pharmaceuticals**, **Axon Instrument**s, which was sold to **Molecular Devices** for $140 million, and **Antisense Therapeutics**.

The Biocreator model is more than passive: "We help with patents and other things. We don't just provide the money." The approach has resulted in the incubating of projects for many years and working very closely with the project scientists. Serry also said that another benefit of the model was that of providing entitlements to Circadian shareholders (through spinouts), so that shareholders would get some returns sooner. Another element of the model was the approach taken towards asset ownership, in which universities (or similar) took equity stakes in project assets or companies. "With the universities, you are a partner in the same investment" said Serry.

One of the issues for Circadian over the years was the problem of dilution. "If we kept on raising funds we would have diluted the shareholders." As it was, Serry's stake in Circadian has been reduced from 65% at foundation to currently 5%, so personally he has been watered down.

Serry said that another significant investment was that made in **Amrad**, which gave rise to an investment position in **Avexa**, both of which created substantial shareholder value.

"Rightly or wrongly" Circadian had created since its listing the conditions for other biotech listings that have followed. There are now more than 120 listed biotechs (The *Bioshares* count is greater than 130), compared to 89 in the UK, 41 in Germany and 9 in France. Serry was awarded a standing ovation from the best attended Life Sciences Lunch Club meeting, which was well attended by both members of the broking community and the biotech business community.

For a man with a penchant for documenting his many ideas by writing them down on yellow post-it notes at home, the event was a worthy tribute to that rare individual, a man who has run a profitable biotech company and delivered real cash returns to shareholders.

Bioshares

Biotech Management Series

Risk Mitigation

Pete Bradley – Principal, Qatalyst

Risk is essential, even desirable

It is almost axiomatic in the biotechnology business world that risk is essential, even desirable. The business of new therapeutics is one where entrepreneurs, managers and funders risk dollars, time and expertise against the potential of great rewards.

Risk can be defined as the combination of the probability of an event and its consequences (ISO/IEC Guide 73). In business it has been defined as "the threat that an event or circumstances will adversely affect the company's ability to achieve its business objectives and execute its strategies successfully".

What is risk mitigation?

Broadly, risk mitigation can be viewed as the identification, quantification, management, monitoring and vigilance of potential hazards. This will allow pre-emptive actions to maximise the chance of success of a project or activity Risk mitigation should be a continuous and developing process which runs throughout the company's strategy and the implementation of that strategy. It should address methodically all the risks surrounding the company's activities past, present and, in particular, future. Easy to say, harder to do.

Medical biotechnology companies face many risks that are common amongst all areas of therapeutic and device product development and many that are specific to particular projects. These risks can be split into three main categories.

External

Risks can arise from the external environment over which the company can exert little if any influence, e.g, availability of finance

Internal

Risks can also arise internally and are ones over which over which the management has complete control, e.g., managing a balanced portfolio of projects, with the ability and fortitude to initiate or kill projects rapidly

An amalgam of internal and external factors

Finally there are risks that are an amalgam of internal and external factors over which management can exert some influence, e.g. investor understanding - during the development of any biotechnology company, investor enthusiasm for its technology and products will naturally wax and wane

The need for controls and reporting systems that address all these risks is taken as a matter of course by a number of investors, but many boards just focus on internal financial control and miss the veritable minefield of risks that surround them. The Turnbull Report published in the U.K. in 2000 states that "all listed company boards must either make an annual statement to their owners of their board processes for risk assessment and subsequent decision making, or they must make a public statement as to why they are not doing so"; this is now built into London Stock Exchange requirements. Closer to home ASX Principle 7 "Recognise and Manage Risk" requires a company to; "Establish a sound system of risk oversight and management and internal control.

This system should be designed to:

- identify, assess, monitor and manage risk; and
- inform investors of material changes to the company's risk profile."

But why so important for biotech?

Irrespective of the legislative requirements, why is it important for biotech companies to identify and mitigate risk? Simply put - our industry is a very high risk industry. As with any business, we have to deal with the standard business risks of statutory, financial and personnel management including occupational health and safety, training and performance management of employees, security for people, facilities and intellectual property. In addition we have risks due to the uncertain nature of the science (technical risk), interpretation of data, clinical trial recruitment and management, reimbursement and the rising expectations of the regulators. As an example, in the future it is envisaged that regulatory decisions will be in part based on risk/benefit analyses rather than data on average outcomes. The complexity of the analysis to be performed will thus increase.

These challenges are real and apply to all biotechnology companies, but there are risks specific for diagnostic, medical device, small molecule, drug and biological product developers.

Diagnostic companies

In many segments of the diagnostics market, diagnostic companies are in an environment where there is no longer any dominant technological design. The advent of quick affordable molecular biology tools coupled with advances in proteomics means that a primary driver here is time. Competitors can enter the market more quickly so marketing and product placement are critical risk frontiers.

As product life cycles get shorter time is a critical issue for the medical device developers too. This factor along with defining study endpoints (blind studies are rare) and establishing quality systems and manufacturing make devices a particular challenge.

Cont'd over

How do biotech companies do what they do?

Many of the activities conducted by life science firms are not self-evident, so we have selected a dozen different topics covering the major aspects of biotech company management as the subjects of contributions from biotech CEOs and exeperienced executives. We hope the series, which we commenced lat last year will both inform and educate. This fourth in the series covers risk mitigation.

The increasingly blurred interface between devices, biological and drugs is also raising regulatory questions that require extensive questions to be answered.

Drug development (small molecule) companies

Small molecule companies find themselves strangely enough in a similar space to device companies. The study, design and identification of correct endpoints are critical to the preparation of the regulatory dossier for the correct indication demonstrating the appropriate efficacy. The recent uncertainty caused by the equivocal results from the four year **Merck - Schering Plough** ENHANCE study of Vytorin demonstrate the critical nature of getting study design right. Post marketing surveillance is also critical here. The example of Vioxx and the subsequent fallout requires these companies to maintain extensive information gathering networks. In addition this change of focus has meant knowledge of the mode of action and interactions with other conditions and drugs is a major component of any regulatory submission. The rise of personalised medicine will also impact significantly, resulting in many more molecules targeted at specific patient populations rather than the blockbusters.

Biologics companies

Biologics have perhaps the toughest row to hoe. The regulatory agencies are scrutinising all aspects of the product development pathway. Areas of particular focus are anti-virals, gene therapies and the use of biologics in manufacturing processes. Perhaps the most dramatic example of why the regulators are increasingly nervous is **TeGenero's** TGN1412 which nearly killed all of the participants in its Phase 1 trial. Of particular interest to the risk environment was that TeGenero had only £2 million insurance cover for that trial. The public reaction to this has meant that biologics need to demonstrate with even more thoroughness the precept of "first do no harm" before looking at efficacy. There are significant manufacturing and therapeutic delivery issues that are specific to biologicals. The recent decisions by the FDA not to expand the indications for **Genetech's** Avastin and **Dendreon's** Provenge vaccine are further examples of the conservative approach being taken by the regulators.

Risk mitigation is essential but it will add significant cost to development programs. A small survey of Australian biotech company CEOs estimated the cost of a development program will increase by 20 to 30% if it is managed well for risk. The components of this cost increase are due to:

- a longer time commitment to activities until preliminary data is established
- additional studies to confirm initial findings and define modes of action
- additional opinions from thought leaders
- more time and effort required for regulatory submissions

What if there were no risk mitigation strategies?

These are considerable costs and commitment of resources, but what if there were no risk mitigation strategies? In that case, the board and management would simply be gambling with the investors' funds. In the event of a disaster that could have been prevented by thorough risk mitigation, the consequences may be;

- the possible "fire sale" of assets,
- management changes (opportunities for senior executives to further their careers elsewhere)
- loss of shareholders' funds
- death of the company (and nothing good can happen when you are dead!)
- a worthy diagnostic, device or therapeutic that will not reach the market and potential benefits not flow through to the community.

Bioshares

– Biota cont'd from page 3

Our view is that cash depleting biotechs in general should retain cash for development programs. However, Biota is on a quite different footing to most biotechs. Strong royalty revenues from Relenza are expected to continue, and could increase further if GSK increases production above an estimated annual capacity of 25-30 million treatment units. And the company may gain, if its litigation with GSK is successful, a substantial payment.

Biota is capitalised at $235 million and held cash assets of $52.5 million at the end of the half year with receivables of $28 million.

Bioshares recommendation: **Buy**

Healthlinx – Ovplex Validated for Early Stage Ovarian Cancer

Healthlinx (HTX: 10.5 cents) is a Melbourne-based diagnostic company that has been developing a test for ovarian cancer that is superior to the general cancer marker test, the CA125 test.

It now looks that the company is well on its way to achieving its commercialisation target of first Australian sales in Q3 2008 with pathology lab partner **ARL Pathology** following the receipt of an independent verification report from **Emphron Informatics**.

The main finding of the verification study was that the test had 89.2% specificity and 93.9% specificity for *early* stage ovarian cancer. An ovarian cancer diagnostic is of great benefit if it can correctly identify the disease at an early stage, when treatment options can have a greater chance of success.

An important commercial aspect to the Ovplex test is that the test is designed to fit in with current laboratory procedures and equipment. This strategy should prove to be very important in seeing the test licensed to international pathology or testing firms.

Healthlinx is capitalised at $8 million and held cash assets of $1.1 million at the end of the December quarter. We have previously discussed Healthlinx as one of our top three under $20 million picks (see *Bioshares* 245), and this view is confirmed with the company's recent announcement.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares Model Portfolio (22 February 2008)

Company	Price (current)	Price added to portfolio	Date added
Circadian Technologies	1.025	1.025	February 2008
Patrys	$0.36	$0.50	December 2007
NeuroDiscovery	$0.16	$0.16	December 2007
Bionomics	$0.40	$0.42	December 2007
Cogstate	$0.13	$0.13	November 2007
Ventracor	$0.45	$0.625	October 2007
Sirtex Medical	$3.75	$3.90	October 2007
Clinuvel Pharmaceuticals	$0.35	$0.66	September 2007
Starpharma Holdings	$0.40	$0.37	August 2007
Pharmaxis	$2.82	$3.15	August 2007
Universal Biosensors	$0.85	$1.23	June 2007
Biota Holdings	$1.28	$1.55	March 2007
Tissue Therapies	$0.20	$0.58	February 2007
Probiotec	$1.34	$1.12	February 2007
Phylogica	$0.12	$0.42	January 2007
Peplin Inc	$0.66	$0.83	January 2007
Arana Therapeutics	$1.08	$1.31	October 2006
Chemgenex Pharma.	$0.79	$0.38	June 2006
Cytopia	$0.40	$0.46	June 2005
Optiscan Imaging	$0.26	$0.35	March 2005
Acrux	$1.00	$0.83	November 2004
Alchemia	$0.47	$0.67	May 2004

Portfolio Changes – 22 Feb 2008

IN:

No changes

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

Corporate Subscribers: Phylogica, Pharmaxis, NeuroDiscovery, Biotech Capital, Cytopia, Biodiem, Arana Therapeutics, Starpharma Holdings, Cogstate, Xceed Biotechnology, Incitive, Optiscan Imaging, Bionomics, ChemGenex Pharmaceuticals, Circadian Technologies, Biota Holdings, Stem Cell Sciences, Halcygen Pharmaceuticals, Peplin, BioMD, Impedimed, QRxPharma, Patrys

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	$950	6-10 email addresses

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