ISSN 1443-850X

In this edition...
Asset management in the Australian biotech sector is improving with more restructuring and merger activities announced this. This a continuation of a positive trend.

Our main stock focus is on Clinuvel Pharmaceuticals, a stock we argue has been become very attractive following recent capital market rumbles in Europe.

What might biotech in Australia be like in 2010? A feature based on a talk given by co-editor David Blake on that very question wraps up this week's edition.

The editors
Companies covered: CUV, PTD, UBI

	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)	-8.1%
Cumulative Gain	**200%**
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 239 (2 Novemberr 2007)
ISSN 1443-850X

Bioshares

2 November 2007
Edition 239

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

Efficient Restructuring and Placement Of Biotech Assets Continues

Three years ago investment bankers had almost given up on effecting M&A transactions in the Australian biotech sector. **Peptech** and **Agenix** had twice attempted to merge their businesses and failed, a move that Agenix shareholders would now be lamenting. However, capital and corporate efficiencies from M&A transactions have been well and truly accepted in the biotech sector since 2004, with the number of local and cross border M&A deals with both listed and private biotech companies steadily increasing.

The competition for investor attention on the ASX has become tougher as mining stocks continue to deliver handsome returns for investors and there is a select number of advanced stage biotech companies that now dominate the interest of the limited number of retail investors prepared to invest in speculative biotech plays. Venture capital groups have acknowledged this and are now starting to beef up their investee companies in preparation for share market listings as seen this week by two Uniseed-backed companies.

Adipogen to merge with Chemgenex's metabolic division

Chemgenex Pharmaceuticals has been through a number of transitions throughout its history. The company started out as a mining company and then moved on to become a genomics company with its core assets being its access to genetic population databases and its Israeli sand rat research tool, that provided the basis for the understanding of various metabolic diseases including diabetes and obesity. In April 2004, the company acquired a US oncology company, **Chemgenex Therapeutics Inc**, which changed its principle focus to oncology.

That transformation this week neared closer to completed when Chemgenex announced that all of its non-oncology assets would be merged with a private Queensland company, **Adipogen**. Adipogen has an obesity treatment program in the preclinical development. Its shareholders include **Uniseed** and **GBS Venture Partners**.

For Chemgenex the transaction makes sense because it can focus all of its attention on its oncology business, which accounts for about 95% of the value within the company. Not only does it give management more focus, but it adds clarity for investors in Chemgenex.

For Adipogen, it provides further funding and a broader portfolio, which will suit the venture capital shareholders. A compliance listing of the entity will be sought on the ASX next year. The new business will be called **Verva Pharmaceuticals**. Chemgenex shareholders will receive a proportionate stake in Verva.

Continence Control Systems to merge with Colocare

A second Uniseed backed company, **Colocare**, announced it has merged with the **Biotech Capital** backed company **Continence Control Systems** (CCS). Colocare is developing a

Cont'd on page 3

Clinuvel Pharmaceuticals: "An excellent buying opportunity."

Clinuvel Pharmaceuticals (CUV: 50 cents) continues to stimulate interest as indications for its compound, CUV1647, are expanded. This week the company announced it would be testing the drug candidate for a fifth indication. The company's share price has been savaged this year, falling by more than 60%; first with some profit taking following a 200% gain from November last year, then due the financial market volatility in August, and more recently because of fears that the company's major shareholder, European hedge fund **Absolute Capital Management Holdings**, would exit the stock after signaling to the market that it was in a distressed state.

The fundamentals of the company are stronger than ever before. At the end of September the company had $60 million in cash, two Phase III trials for different indications with the same compound underway, and it will soon have three Phase II trials with CUV1647 for three other indications being conducted. With the drug expected to be submitted for regulatory approval in Europe in just over a year, there is good reason the company has been able to find new institutional investors to absorb any sell down from its largest shareholder should that occur.

CUV1647 is a melanotropic peptide that is also called alpha melanocyte stimulating hormone. It is delivered via a depot injection under the skin that lasts for two months. The compound stimulates the production on the melanin pigment, responsible for skin pigmentation. Melanin absorbs ultraviolet light which thereby should reduce the chance of people developing skin cancers after excessive exposure to the sun.

The latest indication being trialed for CUV1647 is in preventing skin cancer formation in transplant recipients on immuno-suppression treatment. To prevent organ rejection, these patients are on chronic immune suppression treatment and it has become recognised that these patients have an elevated risk of developing skin cancers. In particular, once one skin cancer lesion appears in these patients, the occurrence of further skin cancer lesions escalates rapidly, according to Dr Heather Rogers from the **New York Presbyterian Hospital** who specialises in this field.

Risks...long term use

Clinuvel is not without its risks. Surprisingly the main risk risk is not in respect achieving efficacy, but ensuring the CUV1647 has an excellent safety profile following long term use. To date it has been in continuous use for over one year and been given to over 300 people for various durations. Regulators would like to see this drug in continuous use in trials for two years before it gets approved and evaluated in over 1,000 people in total.

By every measure the drug has shown to be effective to date. A side effect of the treatment is that a 'naturally appearing' tanned skin results from the treatment, which has some advantages and disadvantages. Running placebo controlled trials may be difficult as patients will quickly know who is being given a placebo injection and who is receiving the drug. On the positive side, if the CUV1647 returns an excellent safety profile, its use could be expanded to non-medical use as a tanning drug, an outcome that is acknowledged as possible but one the company is not promoting, giving the previous failed attempts by the company to develop the compound for such purposes.

The delivery system also has its pros and cons. While it is not ideal and will restrict the market for the drug - being delivered by injection every two months - the upside is that it helps contain the use of the drug for assigned medicinal purposes, a point not lost on regulators that would be concerned about unauthorised cosmetic use of the therapy.

The five indications for which CUV1647 is being evaluated are:

- **Sun poisoning** (PLE) – Phase III trial in 150 patients started in May 2007
- **Sun intolerance** (EPP) – Phase III trial in 70 patients started in June 2007
- **Solar urticaria** (acute reaction to the sun) – Phase II trial expected to start in 2007
- **Photsensitivity from cancer treatment** (PDT) – Phase II trial expected to start in 2007
- **Skin cancer prevention in transplant patients** – Phase II trial expected to start in 2007

The first indication to be sought for approval is in EPP, which is a 12-month trial, with European regulatory submission expected to be 12 months ahead of the US.

Organ transplant recipient trial

The trial with CUV1647 in patients who have undergone organ transplants is expected to take two years to complete and will involve 150 patients in Melbourne, Adelaide, Brisbane and Europe. Patients who have developed their first skin cancer will be suitable for recruitment into this trial.

The link between the increased risk of skin cancer in transplant patients has only become apparent in recent years. It is now acknowledged that most solid organ transplant recipients will develop skin cancers. After four years, 27% of all cardiac transplant deaths are from metastatic skin cancers. The chance of transplant recipients developing squamous cell carcinomas is 60-125 times greater than the general population.

In 2000, the Skin Care in Organ transplant Patients Europe (SCOPE) was formed. In 2001 the Post-transplant Skin Cancer Research Group at the **Ohio Sate University** was formed to better understand the factors that contribute to the increased aggressiveness of skin cancer in transplant recipients. And in December last year, the New York Presbyterian Hospital opened a skin clinic specifically for organ transplant recipients, with its aim to prevent skin cancer formation in this population group.

There are approximately one million patients in the US on immune suppression treatment, which is not an insignificant potential market for this drug, with an additional 74,000 organ transplants

Cont'd over

– Clinuvel cont'd

conducted worldwide each year. Whilst other potential indications may be somewhat obscure to readers, as they are to Bioshares, the organ transplant recipient market is very clear.

A recent series of capital markets related negative events present an excellent buying opportunity for this stock. The stock is not without risks, as acknowledged. However, the projects are being driven aggressively and competently. There is the appeal of the drug being in the final stages of clinical development. The company is fully funded to the time it expects to submit the drug for approval, in just over one year, and the risk of not achieving the efficacy outcomes are low. Clinuvel is capitalised at $151 million.

Bioshares recommendation: **Speculative Buy Class A**

Universal Biosensors Signs Agreement with LifeScan

Universal Biosensors (UBI: $1.65) achieved an important milestone this week with the signing of a non-exclusive Master Services and Supply Agreement with **LifeScan Inc**, an affiliate of **Johnson & Johnson** for the provision of certain services in the field of point of care glucose monitoring. The company also announced that it would undertake a $30-$35 million capital raising through a renounceable rights issue, to be completed in early 2008. The agreement with Lifescan is an umbrella agreement that can enable additional glucose test products to be supplied without recourse to a new agreement. It is worth noting that Lifescan determines the commercialisation of the glucose test/s, with product commitment and product launch and performance requirements still under their control. Universal Biosensors is capitalised at $212 million.

Bioshares recommendation: **Speculative Buy Class A**

Peptech Board Changes

Changes were made to the Peptech (PTD: $1.14) board this week with chairman Mel Bridges retiring and Robin Beaumont taking on the interim chairman position. George Jessup, from Startup Australia also joined the board. Following its recent merger with Evogenix, the substantially renewed Peptech board is likely, in our view, to take a vigourous approach to restoring the currently frayed Peptech share price story.

Peptech's lead compound PN0621 also successfully completed a Phase I safety study this week. Peptech is capitalised at $266 million.

Bioshares recommendation: **Speculative Buy Class A**

– M&A, from page 1

continence management system to irrigate the bowel for people who currently use a colostomy bag. The pump technology can reduce or even eliminate the need for a colostomy bag.

CCS is developing a urinary continence control system that uses a pacemaker type device that controls smooth muscle implanted around the sphincter to control urinary flow.

The merged entity provides a broader medical device company. It provides investors with a pipeline of products in the continence management filed, although the markets are distinct, with both medium and longer term development projects. The Colocare system is expected to reach the US market in the next two years, and the urinary continence system would be three to four years away from conducting pilot studies in the US, after which point it might be an attractive acquisition for a major medical device group. To date, the system has been implanted in five patients in Australia.

Colocare will sell its device direct to consumers, with an estimated price of around $3,000. The larger entity will have better access to capital, with an anticipated IPO next year on the ASX, and sales of the Colocare system will also help fund the urinary stress incontinence control system. The merger also helps balance the risk profile of the two businesses..

Summary

We expect to see more M&A activity in the Australian biotech sector. Companies with products on the market or in late stage clinical trials will be targets for acquisition by larger international competitors. Unlisted companies will continue to broaden their development programs and merge with local and international private biotechs prior to listing to provide more attractive and better structured businesses to lure the speculative investor away from the seemingly unstoppable mining juggernaut.

Bioshares

Australian Biotech in 2010

The following discussion is adapted from a presentation delivered recently to the Queensland branch of Ausbiotech by David Blake, co-editor of Bioshares.

How can one think about what the Australian biotech sector might look like in 2010? There are several questions that can be used to frame this discussion, not least an overarching and at this stage a rhetorical question that asks: What will we have to show for 25 years of investment? That assumes that biotech in Australia started to get its legs in the mid-eighties, a period in which companies such as **Biota**, **Bresagen**, **Circadian Technologies**, **Axon Instruments**, **Amrad**, **Peptech**, **Medical Innovations**, and **Qlone** were formed.

Other important questions include one that has been a topic of discussion for many years which is whether the Australia biotech sector can deliver a home-grown pharma (i.e. drug development) success story. Another way to consider growth is in terms of the number of life science firms that might be listed on the ASX - will there be 200 listed small caps? Or can a certain number of companies reach a particular critical mass in terms of will there be ten $1 billion cap companies, exclusive of the current four of CSL, Cochlear, Sigma and Resmed?

Several other questions to contemplate while we consider the outlook for 2010 include:

- what are the X-factor events that might effect the industry in the lead up to 2010?
- what hurdles does the sector face in the future?

Caveat: The context for the following discussion is that of public listed companies. While there are many private life science firms in Australia, the public listed firms dominate the sector in terms of scale and scope of activities and substantial publicly available data is available for these firms.

The financing context

The Australian life science sector has undergone a tremendous financing boom. A estimated $731 million has been raised in the first three quarters of 2007, significantly higher that the estimated $613 million raised in CY2006. And this is in stark contrast to 2002, when an estimated $100 million was raised. On a cumulative basis at least $3.1 billion has flowed into the sector in financings since 2002. Add this to an estimated $0.5 billion that washed into the sector in the 1999-2000 period. Total cash inflows may be closer to $4 billion for the period 1999 - 2007 if fundings from the exercise of options and other income sources were included.

The increase in the flow of funds is reflective of the deepening of the capital requirements of a number of Australian life science firms, their desire to fund more later stage aspects of development and their capacity to secure funds from a wider range of suppliers of capital.

However, the absolute sum of capital inflows does set up questions regarding investment performance and economic returns to the owners of these enterprises.

The state of the listed sector

In attempting to forecast how many life science companies might be listed on the ASX in 2008, it is worthwhile to examine the current state of the listed sector in terms of aggregate number and value but also look at number and value and average value on a sub-sector basis.

The Australian listed life science sector comprised of 131 companies as of June 30, 2007. This is 300% increase on the 32 companies listed at June 30, 1999. (see Table 1) The sector has experienced two years of significant company inflow, with 20 companies entering the sector through IPOs or back-door listing in FY2001 and 31 companies entering the sector in FY2004. A total of 15 companies (or 10% of 146 companies) have exited the sector either through sale to, or merger with another company, or re-structure and focus on new business activities.

When examined on a sub-sector basis, the largest sub-sector by number of companies is the therapeutic products sub-sector (TPD), where 41 companies account for 31% of the total number of companies. The next largest sub-sector is the diagnostics sector (23 companies; 18%) and then the devices sector (20 companies; 15%).

Table 1: Number of ASX Listed Life Science Firms

Quarter	Total	Nett change	Subtractions	Additions
30-Jun-99	32			0
30-Jun-00	45	13		13
30-Jun-01	65	20		20
30-Jun-02	74	9	2	11
30-Jun-03	79	5	2	7
30-Jun-04	109	30	1	31
30-Jun-05	120	11	2	13
30-Jun-06	128	8	2	10
30-Jun-07	131	3	6	9
30-Sep-08	134	3	2	5
Hypothetical outlook				
30-Jun-08	143	9	5	14
30-Jun-09	150	7	3	10
30-Jun-10	154	4	3	7

On a value basis, that is according to the sum of the capitalisations of each firm, the largest sub-sector is the pharmaceutical sector ($18.8 billion; 55%), followed by the devices sub-sector ($8 billion; 23%) and then therapeutic products ($3.8 billion; 11%).

On an average value basis, it is instructive to note that the average value of companies in the device sector at June 30 2001 was around $400 million, approximately four times the average value of the therapeutic product device companies ($93 million) and the drug delivery companies ($95 million). The device sector includes the profitable revenue generating companies **Cochlear**, **Resmed** and **Sirtex Medical** and also the non-profitable emerging device

– Australian Biotech in 2010 cont'd

companies such **CathRx**, **Ventracor** and **Heartware**. This analysis is important because it underscores discussion about the likelihood of seeing a home-grown pharma company emerge by 2010, if that company is meant to be engaged in the business of therapeutic product development. Only two Australian therapeutic product (drug) developers have ever been profitable and that is Biota (in FY2000 and again in FY2007) and Peptech, and then only on the basis of royalty income not direct product revenues.

By June 2010 the Australian listed life sciences sector may include up to 155 companies. This figure is based on the assumptions that around ten IPOs take place in FY2009 and seven IPOs take place in 2010 and it also assumes an annual attrition of three companies. A key issue is whether there is a large enough private pool of companies for these IPOs to originate. A run through of the portfolios of several venture capital firms yields a sufficient number of companies to make the 17 IPOs realistic. However, it is by no means certain that all of these companies would IPO, with a number likely to be divested through trade sales, and some may even be wound up. However, there exists a sufficient number of private companies outside of these VC portfolio companies that could IPO between now and June 2010, which makes the estimate of 155 companies a reasonable calculation. The figure could also be higher should any number of international biotech firms consider a listing on the ASX.

Table 2: Number of ASX Listed Life Science Firms, by sub-sector

Quarter	Agbio	Comp. Med.	Therap. Pdt. Dev.	Drug Del.	Devices	Diag.	Invest.	Manuf. & Distrib.	Pharm.	Products	Services	Total
30-Jun-99		3	8	1	3	5	2	3	3	3	1	32
30-Jun-00	1	5	13	1	5	5	2	3	4	5	1	45
30-Jun-01	1	5	24	3	8	7	3	4	4	4	2	65
30-Jun-02	1	5	25	3	11	11	3	4	3	5	3	74
30-Jun-03	2	5	26	3	12	11	3	4	5	5	3	79
30-Jun-04	3	5	34	5	17	17	4	6	7	8	3	109
30-Jun-05	3	5	42	7	19	15	3	9	7	7	3	120
30-Jun-06	3	5	44	7	21	20	3	8	6	7	4	128
30-Jun-07	3	5	41	6	20	23	3	9	6	8	7	131

Table 3: Number of Therapeutic Product Firms by sub-sector

Quarter	Biologic.	Cell Therap.	Genomic	Oligo	Peptide	Semi - Syn.	Small Mol	Syn. Hormone	Therapy Other	Vaccine	Total
30-Jun-99	2				1	1	3			1	8
30-Jun-00	3		2		1	1	4			2	13
30-Jun-01	5	1	3		2	1	9			3	24
30-Jun-02	5	1	3	1	2	1	9			3	25
30-Jun-03	4	2	3	2	2	1	9			3	26
30-Jun-04	4	3	2	2	5	2	11	1	1	3	34
30-Jun-05	4	5	1	2	8	2	17	1	1	1	42
30-Jun-06	5	5	1	2	7	3	19		1	1	44
30-Jun-07	2	4	1	2	7	3	19		2	1	41

An even deeper examination of the therapeutic product sub-sector also reveals some interesting facts. Approximately half the companies in this sub-sector are small molecule drug developers, which also means that nearly one in seven Australian listed life science companies are small molecule drug developers. It is not surprising given that the small molecule drug development is an appealing platform because of the acceptability of the modality to many pharmaceutical companies (that could be eventually become marketing partners). It appears surprising that there are few biological drug development companies as of June 30, 2007. However, this is indicative of heightened commercial interest in these companies, with a number of firms in the area including Evogenix (post-June 30), Gropep and Zenyth Therapeutics being acquired.

How many companies by June 30, 2010?

Since June 30, 2007 the life sciences sector has gained two companies, net of departures (**Eqitx**, **Acuron** and **Evogenix**) and new entrants (**Impedimed**, **Hexima**, **Patrys**, **Helicon Group**) and the relisted **Vita Life Sciences**.

There are as many ten companies that could potentially list by June 30, 2008, with at least two that might exit the sector. (**Visiomed** is one that has announced a merger with **Clinical Cell Culture**).

Will there be ten $1 billion cap companies?

An investigation about the possibility of there be being more than ten companies capitalised at greater that $1 billion (exclusive of the greater for large cap listed life science firms of CSL, Cochlear, Resmed and Sigma Pharmaceuticals) starts with an analysis of the sector by capitalisation sector. The next step is to establish a set of criteria by which a potential $1 billion cap company might be identified.

Why does the question matter? A drawback to investing in ASX listed life science companies for many potential investors is that there are not enough companies that meet their requirements by way of capitalisation and liquidity. As the number of companies that grow in value and cross the thresholds of $100 million, $500 million and $ 1 billion capitalisation, then the prospects for certain investors, particularly institutional investors, to invest in the sector increases.

While the life sciences sector is dominated by companies capital-

– Australian Biotech in 2010 cont'd

ised at less $100 million (103 companies, or about 80% of total), the most promising trend has been in the growth of companies capitalised at in the $200-$300 capitalisation strategy. There were nine in this category at June 30, 2007, five more than at the same time a year ago.

There has not been a strong rate of growth in companies capitalised at greater than $500 million, with the number of companies in this category drifting between three and six over the last few years. The small number of companies in this category is a first indicator that the chances of the Australian life sciences sector generating ten $1 billion cap companies by 2010 are slim.

Table 4: Number of ASX Listed Life Science Firms, by capitalisation category

Quarter	<$10M	>$10M, <$20M	>$20M, <$50M	>$50M, <$100M	>$100M, <$200M	>$200M, <$300M	>$300M, <$500M	>$500M, <$1000M	>$1000M	Total
30-Jun-99	8	5	7	3	2	1	2	2	2	32
30-Jun-00	3	7	14	6	6	1	3	1	4	45
30-Jun-01	12	4	15	13	8	3	6		4	65
30-Jun-02	15	8	21	13	9	1	2	2	3	74
30-Jun-03	15	10	25	12	5	3	1	5	3	79
30-Jun-04	18	23	28	14	10	6	2	3	5	109
30-Jun-05	26	26	30	17	7	6	1	2	5	120
30-Jun-06	35	27	27	15	12	4	2	1	5	128
30-Jun-07	25	27	26	25	10	9	3	2	4	131

What makes a $1 billion cap company?

The following criteria for what makes a $1 billion cap company are not necessarily applicable to every candidate that achieves that market valuation category.

A potential $1 billion cap company is likely to have products:

- in or near market, with potential for high revenue growth off base sales in the range $50-$100 million range
- that offer clear and competitive benefits
- that can enter multiple markets or opportunities, or can generate numerous income streams
- that have demonstrated a good safety record
- that demonstrated early and strong insights into efficacy and benefit
- that can be made to a cost of goods (cogs) appropriate to the product value chain

A potential $ 1 billion cap company is likely to have management which is articulate and experienced across clinical, regulatory, partnering, M&A, manufacturing and finance areas.

A biotech company that meets some or all of the above criteria also must consider the important issue of investor demand as it seeks to achieve a $1 billion capitalisation. While the fundamentals of company valuation must always be met, weak investor interest can mean that stocks do not rise to intrinsic valuation levels, or parity valuation levels (ie with international benchmarks), when investor interest is with other sectors. Investor demand has played against the biotech sector in recent years, with investor interest being absorbed by opportunities in the mining and resource sectors.

Another criterion that has emerged as potentially important is that the company has a adopted a fundraising ethos that is not milestone based. This approach has been voiced by the CEO of Pharmaxis, Alan Robertson, who said recently in the context of a $50 million fund raising that *"we are raising funds to make Pharmaxis a profitable and going concern…raising funds on a milestone basis is not a way to build a profitable business"*. In other words, companies should be funded on the basis of the capital required that is necessary to generate profits. This is a view that sits in contrast to the business plans of some Australian biotechs that place capital requirements in second place to investment crystallisation opportunities.

$1 billion cap candidates

One the basis of the selection criteria listed above five companies *stand out today* as potentially reaching a $1 billion dollar capitalisation by 2010. These are **Pharmaxis**, **Acrux**, **ChemGenex Pharmaceuticals**, **Peplin** and **Sirtex Medical**. While there exist other companies that might also reach the $1 billion mark, these companies stand out because there is a greater degree of clarity surrounding these companies at the product level, the management level and at the investor level. What links almost all five of these companies is exceptionally strong determination by management to as rapidly as possible build real businesses with an unambiguous focus on product development and even franchise development.

Co-factors for success

Achieving a $1 billion capitalisation, in fact generating any necessary but warranted up-lift in a company market valuation, is dependent on a number of other factors.

Analyst coverage

Securing and maintaining coverage by biotech analysts is vital in educating investors. The broader and more sustained the coverage becomes, then the greater the level of scrutiny becomes; a company's business model and management is assessed with vigour and depth. If a sustained higher level of scrutiny finds weakness, then a process of correction can take place that either contributes to stock price gains, if addressable in the sort term, or

– Australian Biotech in 2010 cont'd

stock price declines, if the weaknesses are more significant.

Communicate and educate
A company's ability to both communicate and educate a wide variety of audiences is also important, as is its role as an industry leader. Companies that act on the periphery of the sector and do not contribute to forums that address industry problems miss an opportunity to educate potential investors of the relevance and rewards of investing in the life science sector.

A viable board
For biotech companies to succeed and to reach threshold capitalisation marks such as the $1 billion level, they must have viable boards. A viable board is one that is a functional (is not subject to conflict) and dedicated to building the business. A viable board is also structured appropriately to the stage of development of the firm and is made up of members who bring relevant skills and experience to the company.

Business values
A final co-factor is that of values, specifically that a successful biotech firm exhibits business values. What are these values? Business values include placing importance on meeting deadlines and reaching performance targets, working within budget constraints, identifying, quantifying and understanding customers or potential customers' needs and requirements, and communicating clearly and effectively with suppliers, partners and customers.

Hurdles, issues and challenges

While there are many issues and challenges for the Australian listed life science sector, there are several that are worth highlighting.

Competitive intelligence
The investment and product development decisions made by Australian biotech firms could be improved by the resourcing of a competitive intelligence function. Competitive intelligence goes further than market and marketing research to include the ongoing identification of emerging threats and opportunities.

Lack of aggression
Many Australian biotech firms (there are some notable exceptions) lack the level of aggression that can signal to investors, potential partners and customers that the business of drug or device development *and of wealth creation* is taken seriously.

Getting through to stockbrokers/advisors
It is assumed by some that stockbrokers (advisors) have a short attention span. While they may have limited time, when a stockbroker wants to know every thing about an investment opportunity they can be inclined to do intensive research and become extremely knowledgeably about a stock. A challenge for Australian listed life science firms is to persist in their efforts to 'get through' to stockbrokers.

Project management skills
Academic research projects, from where many product development opportunities spring, are not typically managed with pharmaceutical or medical device industry standards of project management. As junior Australian biotech companies emerge from the pre-clinical proof of concept stage of development they need to commandeer and exploit the skills needed to manage a complex weave of clinical trial management, manufacturing development, design and engineering (if device oriented), regulatory and pre-marketing tasks.

Sound medical hypothesis and sound commercial argument
While not at all new to the investment community, what is new is that biotech companies must select products for development according to a sound medical hypothesis regarding the treatment of a disease *and* also link this with a sound commercial argument.

Is it a business?
It could be argued there are two types of biotech companies listed on the ASX which include companies that are the managers of investments in projects and companies that are focused on building businesses that have the goal of making sales and profits. Companies structured and managed as a coherent business are more likely to make apply strategies that decrease investment risk and increase long term shareholder value.

X-factor events

X-factor events are events categorised by economic or business forecasters that are unexpected, to which probabilities have not been assigned. They are often singled out *post facto*. However in the spirit of X-factor analysis, a set of X-factor style events with positive ramifications, and set of events with negative ramifications are proffered for discussion.

Positive events
Virus-based economic threat
A virus-based economic threat could trigger positive sentiment towards the biotech sector. This occurred with the SARS outbreak and with avian influenza, with a positive impact on firms with assets and expertise in those areas. Virus-based economic threats have the capacity to engage the attention of a very large global audience, in ways that chronic diseases do not.

Clinical trial breakthrough
High unexpected success from a clinical trial, similar to the results that emerged from Genentech's combination therapy trial of Avastin in 2003, could bias investment sentiment quickly and favourably to any companies working in a similar area,

CSL splits in two
If the local heavy weight demerged its blood products business, such an event might find favour with many investors, and re-ignite interest in an already very successful investment story.

Acquisition raids
The rapid acquisition of half a dozen biotechs, whether public or private, would serve as a an example of the real wealth generation potential to sector-neutral investors.

Cont'd over

– Australian Biotech in 2010 cont'd

Negative events

Corporate fraud

No business sector is immune from corporate fraud or malfeasance, and biotech is no exception. Should an event in this category transpire, it may exhibit the traditional traits of commercial fraud, but nevertheless intentional deception (heavily disguised) would be a core element.

More pharma failure

The global pharmaceutical sector has continued to experience clinical trials setbacks, product withdrawals and a low rate of drug approvals. Even worse performance could harm the way in which the junior biotechs are perceived by sector-neutral investors.

Deaths in clinical trials

The worst drug-related adverse event in a drug study is where a patient dies. An event of this kind could initiate concerns about all human clinical trials being conducted by Australian biotech companies, even though they may not be working in the same field.

Poaching of top-line management

At the top end, a number of high calibre managers are emerging amongst Australian biotech companies. These managers may become much sought after prizes by international firms or even by other non-biotech Australian companies. Losing competent leadership while the sector is maturing could be a root of a significant setback to value creation in the local life sciences sector.

Conclusion

Can Australia generate a home grown pharma (drug development) success story? The answer is yes, with Pharmaxis the current likely candidate. When this might be is hard to say. Could there be 200 life science listed on the ASX by 2010? There answer is that 150-160 is more likely. Could there be ten $1 billion cap stocks (outside of Cochlear, Resmed, CSL and Sigma) listed on the ASX by 2010? The answer is maybe two and possibly four companies could achieve this status, with one, Pharmaxis already well on its way.

Bioshares

Bioshares Model Portfolio (2 November 2007)

Company	Price (current)	Price added to portfolio	Date added
Ventracor	$0.72	$0.63	October 2007
Sirtex Medical	$4.90	$3.90	October 2007
Clinuvel Pharmaceuticals	$0.50	$0.66	September 2007
Progen Pharmaceuticals	$2.87	$3.52	September 2007
Starpharma Holdings	$0.42	$0.37	August 2007
Pharmaxis	$4.35	$3.15	August 2007
Circadian Technologies	$1.26	$1.45	June 2007
Universal Biosensors	$1.65	$1.23	June 2007
Biota Holdings	$1.36	$1.55	March 2007
Tissue Therapies	$0.45	$0.58	February 2007
Probiotec	$1.25	$1.12	February 2007
Phylogica	$0.22	$0.42	January 2007
Peplin Inc	$0.85	$0.83	January 2007
Peptech	$1.14	$1.31	October 2006
Sunshine Heart	$0.16	$0.19	September 2006
Chemgenex Pharma.	$1.15	$0.38	June 2006
Cytopia	$0.49	$0.46	June 2005
Optiscan Imaging	$0.39	$0.35	March 2005
Acrux	$1.33	$0.83	November 2004
Alchemia	$0.68	$0.67	May 2004

Portfolio Changes – 2 Nov 2007

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, Cygenics, Cytopia, Biodiem, Peptech, Starpharma Holdings, Cogstate, Xceed Biotechnology, Incitive, Optiscan Imaging, Bionomics, ChemGenex Pharmaceuticals, Medical Therapies, Circadian Technologies, Biota Holdings, Stem Cell Sciences, Halcygen Pharmaceuticals, Peplin, BioMD, Impedimed

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