

**In this edition...**

The Chinese healthcare market is huge and alluring. However, we are sceptical when companies such as Polartechnics set their sights on that market.

A more attractive sector may be the antibody field. Dr Merilyn Sleigh, the CEO of Evogenix, provides valuable insights on the main players in the field and how and why some companies have been a success.

**The editors**

**Companies covered:** PLT

**The Bioshares 20 Index**

Change from June 30, 2006  
Change - week ago

-2.9%  
-1.8%

Change - 13 June (Low)

0.5%

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 (from 5 May '06)	-16.7%
<b>Cumulative Gain</b>	<b>132%</b>
<b>Average Annual Gain</b>	<b>21.1%</b>

Please note that last week's cumulative gain was incorrect. It should have read 129%.

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# Bioshares

15 September 2006  
Edition 184

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

## Biotech Sector's Cash Resources Total \$960 Million

With the completion of the reporting season, we are able to provide a more complete picture of the financial position of Australian listed biotech companies. In edition 178 we reported the cash balances held by 88 companies required to report their cash positions under the ASX's 4.7B reporting rule. We have now been able to compile cash flow statement data for an additional 27 companies. We have calculated Survival Indices for 16 of those companies that are essentially cash burning companies lacking revenues of significance.

Overall, for 115 companies, including another eleven revenue generating companies, covered in this analysis for FY 2006, we calculate that a total of \$960 million is held as a cash resource, 10% greater than was held at June 30, 2005. Excluding these eleven companies, we record that the remaining 104 cash burning companies managed cash assets of \$884 million, sufficient to fund 1.8 years of operation, based on net operational cash flows for FY2006.

As a group, the 4.7B group of companies had funds sufficient to fund 1.6 years of operations, whereas the 16 non-complying 4.7B companies had funds to support 2.5 years of operations. For the latter set of companies, the company with the most favourable Survival Index was Biota (6.0) followed by Circadian (5.1), Zenyth Therapeutics (5.0), Cytopia(3.7), Progen Industries (2.4), Metabolic Pharmaceuticals (2.3), Novogen (2.1), Ventracor (2.0), Chemgenex Pharmaceuticals (1.8), Optiscan Imaging (1.4), Eiffel Technologies (1.2), Phosphagenics (1.1 - half yearly figures annualised), Agenix (1.0), Virax (.08), Anadis (0.5) and Polartechnics (0.2). Investors should note that Survival Indices are of limited benefit as they do not take into account future capital considerations of biotech firms. However, they are often useful in identifying companies with more pressing and immediate fund raising requirements.

Cash Resources - at June 30	2005	2006	Survival Index
	\$M	\$M	
4.7B Reporting Companies (88 Companies)	\$527	\$591	1.6
Pre- 4.7B Rule Companies (16 Companies)	\$265	\$294	2.5
<b>Sub-Total</b>	<b>\$792</b>	<b>\$884</b>	<b>1.8</b>
	(104 Companies)		
Revenue generators (11 Companies)	\$80	\$76	Not App.
<b>Total</b>	<b>\$872</b>	<b>\$960</b>	

Correction: re CyGenics [Edition 183] the statement that 16 million shares were released from escrow in the last week was incorrect. The shares were released from escrow in June.

## Polartechnics' Bold Forecast

Polartechnics (PLT: 11.5 cents) has revealed ambitious sales forecasts for sales from its TruScreen cervical cancer screening device and consumables. The company announced in July that it had signed an agreement with **Global Medic Tech Ventures Pte Ltd**, from Singapore, for the distribution of Truscreen into mainland China. Truscreen is a probe-based technology that uses electrical signals and light waves to detect cancerous lesions in the cervix. Its principal competitor is the pap smear.

The agreement specifies an initial order for 250 consoles and associated handpieces, and a minimum of 2 million TruScreen Single Use Sensors (SUS) per annum. According to the agreement, minimum sales of \$15 million are guaranteed for FY2007/08.

Entry into the China market is dependent on approval from the Chinese Ministry of Health and completion of clinical trials in China. A related dependency is the completion of new production facilities at Botany, Sydney.

### Truscreen History

Polartechnics listed on the ASX in 1987. The company signed a global marketing and distribution agreement for Truscreen with **Ethicon**, a subsidiary of **Johnson & Johnson**, in 1997. The agreement saw Polartechnics retain rights for Australasia, Taiwan, Korea, Philippines, Singapore, Malaysia and Indochina.

The Ethicon agreement lapsed in April 2004. This was a major setback for the company. However, global marketing rights reverted to Polartechnics, enabling the company to focus, as it now planning, on markets such as China and India. The company received CE mark approval, permitting the marketing of Truscreen in Europe in November 2001. Australian approval was obtained prior to this date. Marketing approval was received for Truscreen in Singapore and Malaysia in June 2005. Sales of Truscreen have been negligible to date, with approximately \$100,000 recorded in both FY2005 and FY2006.

### Capital raising

In the ten years since 1997, the company has secured \$61 million in funding from the Australian equities market. Polartechnics is currently looking to raise an additional \$1 million to \$1.5 million through a share purchase plan, and another \$3 million to \$4 million through a private placement or convertible note issue. The company has also flagged the possibility of a listing on the Alternative Investments Market in London.

### Change in management

The company's management changed in January 2006, following a period of board instability. The company's current CEO is Ben Dillon, who is a former KPMG partner and executive with Macquarie Bank and Westpac bBank. Other members of the board include executive chairman Robert Hunter (an accountant) and Professor Neville Hacker (a gynaecologist and oncologist). The board lacks members with specific medical device commercialisation and marketing experience.

### Polartechnics' Sales Growth Outlook

(Reproduced from company presentation 8 Sept. 2006)

	2005 Actual A\$000	2006 Estimate A\$000	2007 Plan A\$000	Outlook Year 3 A\$000
<b>Womens Health</b>				
<b>Truscreen</b>				
Australia/Italy	107	100	100	100
China			*6000	50,000
ASEAN				10,000
Middle East				4,500
			15,100	64,600
<b>Skin Therapies</b>				
SolarScan: Australia	1,100	1,400	2,500	3,000
SolarScan: UK/NZ				3,000
MediScan: Australia/UK	1,300	800	1,500	3,000
Skin Therapy Devices: Aust	3,500	4,100	5,500	10,000
	5,900	6,300	9,500	19,000
	6,007	6,400	15,600	83,600

\*Assumes China sales commence March 2007

### Analysis

Polartechnics under its old management failed to turn the Truscreen technology into a profitable business. However, the goal of the new management to generate a net profit of \$15 million in three years, based on a strong contribution from growth in sales of Truscreen in China, is very ambitious. The legal and economic system in China is, despite certain advances, a highly risky place to conduct commercial activities, with the capacity to protect property rights and receive compensation for theft or infringement of property rights still well below levels acceptable in 'Rule of Law' economies. Although Polartechnics is accessing the China market through a channel partner out of Singapore, GMTV, the China market risk still applies to Polartechnics. Polartechnics could benefit from supplying more complete details of its agreement with GMTV, especially pertaining to the clauses that allow GMTV to renege on the deal. Polartechnics is capitalised at \$11.6 million.

### Bioshares recommendation: Sell

#### Bioshares Model Portfolio (15 September 2006)

Company	Price (current)	Price added to portfolio
Acrux	\$0.71	\$0.83
Agenix	\$0.15	\$0.22
Alchemia	\$0.69	\$0.67
Avexa	\$0.220	\$0.15
Bionomics	\$0.15	\$0.210
Biosignal	\$0.17	\$0.22
Cytopia	\$0.670	\$0.46
Chemenex Pharma.	\$0.46	\$0.38
Evogenix	\$0.410	\$0.47
Optiscan Imaging	\$0.470	\$0.35
Mesoblast	\$1.250	\$1.27
Neuren Pharmaceuticals	\$0.46	\$0.70
Pharmaxis	\$1.92	\$1.90
Prima Biomed	\$0.062	\$0.09
Sirtex Medical	\$2.25	\$1.95
Sunshine Heart	\$0.19	\$0.19

Portfolio changes

Sunshine Heart has been added to the Bioshares portfolio at 19 cents

### Some Definitions...

**Antibody** - A complex protein produced by cells of the immune system, which specifically recognises a target molecule known as an antigen. A key component of the body's defence mechanisms.

**Monoclonal Antibody** - An antibody of a single type, derived from a group or clone of identical cells.

**Antibody therapeutics** - drugs which comprise a monoclonal antibody. Antibodies make excellent drugs since they recognise targets not affected by small chemical drugs (new ways of treating disease), attach very specifically to these targets (few side effects), and exert their therapeutic benefits for a long time in the body (infrequent dosing).

**Antibody libraries** - Collections of antibodies, which may include billions of different types. An antibody "library", like a database, may be searched (screened) to find the member of the collection that attaches best to a particular target. When antibodies are of human origin, then searching the library will provide a human-derived antibody for further development.

**Humanising antibodies** - engineering an antibody so that it consists mainly of material from a human antibody, while retaining the targeting ability of the starting antibody, which may have come from mice, rats or other animals. Such a "humanised" antibody will no longer be rejected and inactivated by a patient's immune system.

## Winning Business in the Antibody Sector

by Merilyn Sleigh, CEO of EvoGenix Ltd

The following is a written version of a presentation made by Dr Merilyn Sleigh at Bioshares Thredbo Biotech Summit 2006, held in July of this year.

It is a common enough pattern in our world of high technology advances – a breakthrough technology opens up a new field; early adopters move in to utilise the technology at an initially high price; imitators enter the field and undercut the first movers or out-compete them with superior technology; the technology becomes more widely available, prices drop and the technology pioneers either reinvent their businesses to adapt to changing circumstances or are snapped up by large players moving into the field. This is as true in biotechnology as it is for PCs, iPods, or mobile phones.

A sub field of biotechnology where this process can be examined in action is that of antibody therapeutics. Antibodies were initially hailed as the breakthrough that was going to deliver magic bullet therapy, the "selective toxicity" sought in drugs by Australian medicinal chemistry pioneer Adrien Albert as far back as the 1950s. Unfortunately early clinical testing with antibodies (usually generated in mice) represented something of a triumph of hope over scientific rationality. While the treatments were sometimes spectacularly successful at the beginning, the effects were short-lived. The foreign (mouse) protein, when given to a patient, not surprisingly activated their immune system, with rejection of the treatment after a small number of doses.

The real breakthrough came when methods to develop human-like or human-derived antibodies became available - so began the real development of antibodies as successful drugs. The key group of technology pioneers opening up the antibody field were:

**Protein Design Labs** - PDL (USA) - key patents and technology for humanising antibodies by CDR grafting.

**Cambridge Antibody Technology** - CaT (UK) - large libraries of human antibodies and advanced in-house technology for screening these.

**Morphosys** (Germany) - a somewhat later entrant with human antibody libraries, but developed superior screening and selection capabilities more amenable to widespread use than those of CaT.

**Applied Molecular Evolution** - AME (USA) - pioneers of antibody optimisation - making variants of a starting antibody with improved characteristics, particularly increased potency.

**Medarex and Abgenix** (USA) - two companies which developed mice engineered with a partial human immune system, to allow direct generation of "human" antibodies in mice, starting from a drug target - an alternative to mouse antibodies or human antibody libraries.

Antibodies have by now proved themselves to be resoundingly successful in treating otherwise intractable diseases and building very large sales. All of the current blockbuster antibody therapeutics have been generated by the technology pioneers (generally working with a large pharma partner) or by an early-following large biotech. The more successful technology pioneers are now earning royalties from multiple marketed products, with more in late clinical development.

**Table 1 - Five eras for therapeutic antibodies**

1980-1995	Pre-technology era	Mouse antibodies tested in patients
1990-2000	Technology pioneers	Breakthrough technologies for human-compatible antibodies by specialist technology companies
1995 - 2000	Early followers	Large biotechs (Genentech, Centocor, Amgen) entered the field with targets and worked with the pioneers, while developing alternative
2000 -	Imitators	Smaller biotechs entered with different, sometimes better technology. Technology pioneers lost some of their competitive edge
2005 -	Multinationalisation	Larger companies entered the game, swallowing up promising products and technology from both pioneers and later entrants

We are currently entering the multinationalisation phase for antibody therapeutics, as noted in **Table I**. This features a large amount of M&A activity. Numerous transactions since late 2004 have highlighted the desire of large pharma companies to bring in-house the technologies needed for generating new antibody products and to acquire early stage products to fill their pipelines in the interim. Some examples of this activity include

- Eli Lilly acquisition of Applied Molecular Evolution - US\$400 million in 2004
- Abgenix acquired by Amgen - US\$2.2 billion in 2005/6
- CaT acquired by AstraZeneca - US\$1.4 billion in 2006
- Abmaxis (with an imitator antibody optimisation technology) acquired by Merck - US\$80 million in 2006
- Acquisitions focused on accessing antibody products (e.g. CSL bid for Zenyth in 2006; Collective Therapeutics purchase by Medimmune in 2005)

Substantial licensing deals for individual, often early stage, products have also occurred.

Three of the list of antibody technology pioneers are now part of a larger organisation - the other three remain independent. Either acquisition or independent development can be a legitimate direction for a biotechnology company and provide an attractive outcome for investors. Are there particular features of the business strategies of these 6 companies that have led them to their different fates?

The three technology pioneers who remain independent have all taken different strategies to build an integrated and substantial (but not necessarily yet profitable) business, in two cases based completely on their technical strengths.

#### **A strong profit focus at Morphosys**

German company Morphosys has focused on exploiting its HuCal human antibody libraries by lateral expansion into new market segments, and multiple licensing deals. Morphosys has aimed at very broad dissemination of its technology through licensing agreements with a wide range of pharmaceutical partners, going back to 1999. It has a strong customer focus, putting considerable effort into both ensuring that its technology is robust and easily transferable, and training its partners to get the best out of the licensed technology. Any in-house work carried out for partners is strongly profit-focused. Morphosys is also building a strong position in the research antibody area through M&A activity and is now the leading supplier of research antibodies in Europe. A recent alliance with Chemicon has taken it into diagnostics, continuing its focus on extracting maximum value out of its antibody library assets.

Morphosys has built a profitable business from its antibody capabilities and has focused on achieving cash flow to recognise the particular requirements of the European capital market. Morphosys has little if any internal focus on therapeutic products, although it

**CDR grafting** - a process whereby an antibody is humanised by transferring the CDR regions of an antibody (the sections that attach to the target) into a human antibody framework. Antibodies from most species have closely related structures, facilitating cutting and pasting of particular segments from one antibody to another.

**Antibody optimisation** - improving an antibody by making many copies, each with one or more small changes, and then selecting the variant with the required properties. Most often used to increase the tightness of attachment of an antibody to its target. This improves drug effectiveness and can decrease the clinical dose.

**Human antibodies made in mice**  
- mice are genetically engineered such that some of their genes involved in making antibodies are replaced by equivalent human genes. When challenged with an antigen or target, the mice make antibodies which are human in character.

*Cont'd over*

will access some of this blue sky potential through a small royalty share in therapeutics developed by the licensees of its libraries.

**Table 2 - Origins of some antibody blockbusters**

Drug (year introduced)	2005 worldwide sales	Originating company	Company type
Rituxan - anti lymphoma (1997)	US\$ 3.6 billion	Genentech	Early follower biotech
Remicade - anti inflammatory (1998)	US\$ 3.4 billion	Centocor (acquired by J and J)	Early follower biotech
Humira - anti inflammatory (2003)	US\$ 1.3 billion	Cambridge Antibody Technology (CaT) for large pharma	Tech pioneer with large pharma
Synagis - anti viral (1998)	US\$ 1.1 billion	Protein Design labs for Medimmune	Tech pioneer with medium pharma
Avastin - anticancer (2004)	US\$ 1.3 billion	Protein Design labs for Genentech	Tech pioneer with early follower biotech

### **Medarex's multiple partnerships**

While notable for its transgenic mouse technology for generating human antibodies, Medarex has focused on capturing value from this technology through multiple partnerships and a particular liking for product co-development arrangements. The Medarex website lists around 60 agreements and interests in 30 products in clinical phase, several in Phase III. One significant feature of the Medarex list of alliances is the large number of small to medium biotechnology companies. Medarex has recognised that these companies can often

bring significant expertise and IP assets around drug targets, but may lack some of the skills and finance to move their products past the research phase. Medarex accesses the inside knowledge on potential products from these partners, while supplying not only the required antibody discovery technology to get over the initial technical hurdle, but increasingly the manufacturing and clinical expertise as well.

### **PDL Biopharma...out-competed**

Protein Design Labs signalled a name change to PDL Biopharma, in 2005, and an accompanying change in direction and strategy. Finding itself in possession of a technology which was increasingly being undercut and out-competed by newer entrants to the space, PDL has mostly abandoned its antibody roots, firing its expert technologists and acquiring a pipeline of advanced and marketed therapeutic products, most of which are not antibodies. PDL has been able to use the royalty stream it is deriving from products generated for partners in early technology collaborations (US\$130 million in 2005), as well as continued shareholder support, to buy a new business strategy. It is now a drug development, manufacturing and marketing business, with little connection to its technology origins.

Morphosys and Medarex have been able to build businesses which from a relatively early stage were directed towards getting the best out of their technology capabilities, while recognising their areas of relative weakness (access to significant capital for a European company; ability to access appropriate antibody targets for Medarex). PDL was very late to adapt its business model as its technology edge began to slip, and was only able to do so at the last minute because of the strength of its income stream.

The other three companies in the pioneer list have all been acquired by larger industry players, although the motivations behind these acquisitions have not always been the same.

### **Abgenix valued on potential income stream**

Abgenix followed a fairly similar business strategy to that of Medarex, although with a greater focus on technology and some false starts in development of internal antibody products. The bid for Abgenix by Amgen (at a 54% premium to the pre-bid market price) has been attributed to the co-ownership by Abgenix of a potential antibody blockbuster drug in Phase III trials by Amgen. Their bid for Abgenix valued the company essentially at the expected value of this income stream, with a discounted value attributed to the technology assets and other potential royalty interests. Some industry analysts have speculated that Medarex may be susceptible to a bid for similar reasons, although the identity of a potential bidder is less obvious, since Medarex has significant interests in several late stage products with different partners.

*Cont'd over*

### What CaT and AME have in common

Some interesting characteristics are shared by CaT and AME, the remaining targets in the list.

- Both had a primary focus on their technology base and a business strategy centred on in-house collaborative work with multiple partners.
- Where they engaged in their own M&A activity, this had a heavy emphasis on technology consolidation, especially in their earlier stages (CaT attempted a product acquisition by its bid for Oxford Glycosciences in 2003, but was trumped by a bidder with deeper pockets).
- Where they moved to develop their own product pipeline, they did this with mixed success, in the case of CaT characterised by some poor product choices and early clinical failures. AME had an early focus on products but this was not pursued so strongly in later times.
- Both entered major technology relationships with one large pharmaceutical/biotech company working on multiple products in a broadly based deal - this large partner was their ultimate purchaser.

**Table 3 - Market valuation compared with capital invested**  
(all amounts approximate, in US\$ M)

Company	Capital invested post IPO	Market value (current, or pre-bid)	Bid price
CaT	\$460	\$800	\$1,400
Morphosys	\$80 (incl IPO)	\$300	NA
PDL	\$600	\$1,980	NA
Abgenix	\$920	\$1,400	\$2,200
Medarex	\$540	\$1,170	NA

(AME was a private company at the time of its acquisition by Eli Lilly)

These two companies achieved attractive valuations when acquired, based on their technology capabilities and to a lesser extent their interests in the products of others. It appeared that less value was attached to any products being developed in-house. In the case of AME, the technology platform has become fully integrated into the Eli Lilly drug discovery efforts, and it is expected that the same will happen following AstraZeneca's acquisition of CaT.

As **Table 3** shows, company market value in terms of funds invested is variable, with the company operating the most conservative business strategy (Morphosys) relatively the best regarded by the market.

### 126% total return over the 4 years

Regardless of their business directions, companies with significant focus in the antibody sector have proved to be rewarding for their investors. In an analysis of the scorecard for biotech investment, published in *Nature Biotechnology* in July 2006, author Tom Jacobs noted that 4 of the companies discussed above, PDL, CaT, Medarex and Abgenix, between them averaged a 126% total return over the 4 years to February 2006, double that of the AMEX Biotechnology Index, and more than double that of the S&P 500 Index over the same period. (The CaT and Abgenix valuations used were those achieved at acquisition, not their market prices pre-bid.) Genentech, with several antibody therapeutics marketed, achieved a 432% return for its investors between 2002 and 2006.

### Investment Point – a clear business focus

For biotech investors, we can say that if the choice of "where in the market" is correct, then a variety of business pathways can result in good investment returns. However, it is also apparent that those companies that have a clear business focus and successfully deliver on strategies to capitalise on their initial assets are likely to provide the best value for money invested over the longer term

EvoGenix (ASX:EGX) is an antibody-focused company, with operations in Australia and the USA. The company applies its advanced proprietary technology for antibody humanisation and optimisation to build a pipeline of high value therapeutics products, also earning revenues through collaborations with major companies including GlaxoSmithKline and CSL Limited..

## 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.

<b>Buy</b>	CMP is 20% < Fair Value
<b>Accumulate</b>	CMP is 10% < Fair Value
<b>Hold</b>	Value = CMP
<b>Lighten</b>	CMP is 10% > Fair Value
<b>Sell</b>	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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