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**In this edition...**
Peptech has set an unlikely ambition for an Australian biotech company. That is to take its PN0621 anti- TNF-alpha drug (for rheumatoid arthritis) through to the end of Phase III, before it seeks a marketing partner. The company has the cash, IP and know how to do it, so this is not an unrealistic goal. This is a very positive event for the Australian biotech sector.

What do Brainz, Atcor and Cogstate have in common? They are all small 'health information' gathering companies that have products on the market. But how they can grow sales and when they can deliver profits is the key question investors need answered.
**The editors**

**Companies covered: ACG, ACL, BZI, CGS, PTD**

| | 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) | -15.0% |
| **Cumulative Gain** | **136%** |
| **Average Annual Gain** | **21.4%** |

*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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# Bioshares

**29 September 2006**
**Edition 186**

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

## Peptech Aims High

Peptech (PTD: $1.31) has put forward an aggressive but attractive plan to increase its focus on the development of its domain antibody drug, PN0621, and take the compound through to the end of Phase III clinical trials, and then seek a marketing partner. PN0621 targets the TNF-alpha protein. This is an ambitious plan set by Australian biotech company but it is a realistic plan. Peptech can articulate this plan because it has appropriate antibody drug development experience and know how at its disposal, cash assets, both current and prospective, freedom to operate and a patent coverage extending to 2025.

Peptech is the holder of broad patents that cover the binding of monoclonal antibodies or antibody fragments to TNF-alpha. TNF-alpha is a cytokine that is excessively activated in diseases of inflammation such as rheumatoid arthritis. Through its investee company Domantis, Peptech has access to Domantis' domain antibody technology. For PN0621, the company is obligated to pay Domantis a 4% royalty on sales.

Sales of the three leading drugs that modulate TNF-alpha, Enbrel, Remicade and Humira, totalled US$6.5 billion in calender year 2005. These drugs posted a 33% increase in sales for 2005, on the back of a 35% increase in 2004. Growth has been exceptional. What is made transparently clear by these growth figures is that the market for anti TNF drugs is very large and validated clinically and financially. Therefore Peptech's decision to target this market is soundly based. Peptech receives royalties from two of those marketed drugs, Humira and Remicade. Royalty income for Peptech is expected to be in the order of $25 million for the fiscal year ending September 30, 2007, with minimum income following to 2010 of $75 million anticipated.

PN0621 could be expected to compete with existing marketed drugs such Enbrel, Remicade and Humira because of a potential superior efficacy and cost of goods profile. Peptech is the only company, through Domantis, that can develop domain antibodies for the TNF-alpha target. Peptech has already successfully developed high yields from expression systems for PN0621, having now manufactured sufficient quantities for Phase I and II trials. Phase I trials will commence in 2007.

Investors can be confident that Peptech has now convincingly set out to create significant shareholder value by managing the full clinical development of PN0621. Peptech is capitalised at $218 million and held cash of $42 million at March 31.

*Bioshares* recommendation: **Speculative Buy Class A**

Bioshares

**World-wide sales of Anti- TNF-alpha drugs (US$B)**

| | 2003 | 2004 | 2005 |
|---|---|---|---|
| Humira<br>***Abbott Laboratories*** | $0.6 | $0.9 | $1.4 |
| Remicade<br>***Johnson & Johnson*** | $1.7 | $2.1 | $2.5 |
| Sub-total | $2.3 | $3.0 | $3.9 |
| Enbrel<br>***Amgen*** | $1.3 | $1.9 | $2.6 |
| Total | $3.6 | $4.9 | $6.5 |
| % change | | 35% | 33% |

# *Atcor, Brainz and Cogstate: The ABCs of Three Revenue Generating Companies*

Expanding operations into the US market is a pivotal phase for Australian medical product companies. The US represents the largest healthcare market in the world and getting the strategy and entry into this market right is crucial to the success of many companies in this sector. **Atcor Medical**, **Brainz** and **Cogstate** are three emerging small cap medical product companies listed on the ASX that have started this process. Their approaches are all different although there are similarities that warrant comparison. That each of these companies is also in a position to deliver significant revenue growth and to move to profitability also makes them worthy of investment consideration.

Brainz (BZI: 50 cents) is a New Zealand-based company listed on the ASX that has developed a device that allows compressed EEG brain function monitoring primarily for the neonatal care market. Whilst EEG devices are commonplace, Brainz's device, called the BRM2, allows brain function to be immediately monitored at the bedside without the extensive analysis by neurologists.

**Revenue growth**

In the last 12 months to the end of August, the company increased sales of its brain monitors by 95% with receipts from customers just under NZ$1.4 million. The company sold 74 units in this period and subsequent to year's end it sold an additional 19 units. (Note that receipts for the most recent quarter were considerably higher than for previous quarter although this was due to an invoicing backlog). To become profitable, the company needs to sell 280 units a year which excludes consumable sales. Averaging the last 12 months of receipts, the company is has a quarterly burn rate of NZ 450,000 although we expect the company will approach profitability by the end of this financial year. To achieve this it will require device sales to exceed 70 per quarter. The company listed in December 2005 with NZ$11.9 million post IPO and it had NZ$10.1 in cash at the end of August 2006.

**Distribution approach**

Brainz' distribution approach is a combination of direct sales in Australia and New Zealand and through a distributor, **GE Healthcare,** in other major markets. Sales are directed towards hospitals, primarily at this stage for use in neonatal wards. Supplementing its distributor in international markets, Brainz is building a team of support and training staff in the US and the UK. At present it has three full time staff in the US and 11 contracting nurses in the US, two in the UK, and up to four staff/contractors will be hired in continental Europe in coming months. This is in addition to the 22 staff in Auckland where the product is manufactured.

Brainz has recently expanded its distribution arrangement with GE Healthcare to include 35 new territories, including Europe, Canada, the Middle East and North Africa.

**History of operation**

The brain monitor was first released in Australia and New Zealand in 2003, in the US in February 2005 and in the UK in the second quarter of 2005. The product has recently been launched through GE in mainland Europe. The bulk of the 19 sales reported for February were from a backlog for European sales.

**Recurring revenue stream**

The Brainz instrument in Australia sells for $25,000. It's a capital expenditure item however the goal is to get hospitals making multiple subsequent orders for the instruments once the technology becomes accepted as the standard of care for neonates and other departments such as intensive care units.

The company also typically receives ongoing revenue from service agreements and sales of disposables for the instruments which totals in the order of $7,000 a year per installed device. Although this revenue stream at present is relatively insignificant with an installed base of about 180, once this increases to over 1,000 installed units this revenue stream will become important.

**Intellectual property position**

Although Brainz has limited patent protection over its instrument, its core product does have distinct advantages over competing products (see edition #175 of *Bioshares*). The company has developed an additional feature that allows seizure detection over which a patent application has been filed. The seizure detection allows further product differentiation as well as potentially increasing the market size by increasing its use both in the neonatal setting and in adult care in intensive care units. The seizure detection device was launched recently in Australia and New Zealand. It sells for $5,000 as a software upgrade to its core BRM2 brain monitor. The company is awaiting approval to sell the seizure detection upgrade in the US.

There have been several publications detailing the use of continuous EEG monitoring using a method called amplitude-integrated EEG monitoring which Brainz uses as core technology in its device.

**Tipping point**

The tipping point for Brainz – when the commercialisation risk has been diminished significantly – is once this technology begins to be accepted as the standard of care in hospitals and when hospitals begin submitting follow-on orders without prompting from GE or Brainz marketing staff. With just under 200 instruments installed to date, an installation base of over 1,000 will be a sign that the technology has been firmly accepted as a standard instrument in most neonatal wards. If rollout of the product progresses successfully, then this should occur within 24 months.

Brainz is currently capitalised at $30 million.

*Bioshares* recommendation: **Speculative Buy Class B**

# Cogstate

Cogstate (CGS: 20 cents) is another medical products group that is now expanding its operations in the US and UK markets. Directed mainly at pharmaceutical companies, Cogstate delivers a cognitive testing service and product used in the clinical trial setting.

Although the company's revenue stream is concentrated at the moment on use of its product within clinical trials, it has the opportunity to expand the product's use into other markets, such as cognitive testing of employees in the work setting (Alert4Work) and cognitive testing in the broader community (CogHealth) to assess for neurodegenerative conditions such as Alzheimer's disease. The company also continues to generate a moderate ongoing revenue stream from concussion testing under its CogSport product. All products are designed around a similar software program that incorporates playing cards in a testing battery used to measure response times and memory function as part of a broad cognitive testing facility.

**History of operations**

Cogstate was formed in 1999 and listed on the ASX in early 2004. The company's focus was initially on commercialising its cognitive testing platform for use in the broader community to measure memory and cognitive decline. Prior to listing the company had in-licensed two therapeutic programs in the CNS area although these programs have now been closed. Since the beginning of the last financial year the company has concentrated on the clinical trials application of its technology.

**Distribution approach**

Cogstate has opted for a direct sales and marketing approach to pharmaceutical companies. The majority of revenue is generated from the US with some from Europe. Cogstate has two employees based in the US and is shortly to employ a third person in the US to help manage the clinical trial contracts with pharmaceutical companies. The staff are generally sourced from major pharmaceutical companies. The US team is supplemented by key staff based in Australia that make regular visits to the US to help market the product directly to pharmaceutical companies.

**Revenue growth**

Sales in the last financial year doubled for the company to just over $2 million. Earlier this month the company announced it had contracted future work in excess of $2.4 million. Over the last five quarters sales growth has increased almost linearly from just under $200,000 for the first quarter of 2005 to just under $700,000 in the last quarter to the end of June. A reasonable sales target for the company for this financial year would be $4 million, which might see the company reach profitability in this financial year.

**Recurring revenue stream**

Cogstate receives a small recurring revenue stream from its concussion testing service used by sports groups. In the last financial year this totalled just over $200,000. Expanding sales to provide annual cognitive testing of employees in the workplace would provide a high quality of repeat earnings that could build into an important part of the company's overall revenue stream.

In the last financial year sales to the company's main purchaser, **Pfizer**, contributed to 35% of total revenue. Repeat business from the company's existing customer base, together with growing that customer base, we believe are primary objectives for the company. It's encouraging to note that the company has secured initial sales contracts with three large pharmaceutical companies in the last four months. These are with **GlaxoSmithKline**, **Merck** and specialty CNS group **Lundbeck**.

Other major companies that have used the test include **Alza Corporation**, a subsidiary of **Johnson & Johnson**. The company has also provided cognitive testing to functional food companies and earlier this year signed on a Japanese distributor that will pay US$500,000 over two years to access the product.

**Intellectual property position**

Cogstate has been granted a patent that covers its core technology in Australia and has received a Notice of Allowance from the US Patent & Trademark Office.

Results from trials utilising the Cogstate testing platform have been published in over 50 peer-reviewed scientific journals.

Cogstate's main competitor, **Cognitive Drug Research,** based in the UK, has developed a very profitable business in delivering cognitive testing for clinical trials for the pharmaceutical industry over the last 25 years and has been standard use in clinical trials for the last 20 years. Cogstate competes directly with this company, which also offers a computer-based cognitive testing service.

**Tipping point**

The current financial year (FY2007) may be a pivotal year for Cogstate. Profitability is in sight for the company as it seeks to grow revenue from $2 million to our estimates of between $3-$4 million in this financial year. The tipping point for this company is once it has built a secure and profitable base from the clinical trial work, it will then be in a position to expand more vigorously into other markets such as cognitive testing in the work place and broader community testing of cognitive function.

Cogstate is capitalised at $9 million with $2.6 million in cash and equivalent assets.

Bioshares recommendation: **Speculative Buy Class B**

# Atcor Medical Holdings

Atcor (ACG: 18.5 cents) was co-founded in 1994 by Professor Michael O'Rourke, a cardiovascular specialist at **St Vincent's Hospital**, Sydney, and Ross Harricks. The company listed in November 2005, raising $15 million through the issue of 30 million shares at 50 cents per share. The company's share price has performed poorly since listing, despite the company's receipt of regulatory approvals for its SphygmoCor device in key markets and the publication of validating clinical trial data.

*Cont'd over*

**The Atcor technology**

Atcor has developed the SphygmoCor device. This device non-invasively measures blood pressure at the heart based on analysis of wave forms. Central blood pressure can be measured in other ways at the heart, but only invasively if a catheter is used. Traditionally, blood pressure has been measured using a sphygmomanometer and cuff device that is wrapped around an arm and inflated to the point at which blood flow in the main artery is stopped. The sphygmomanometer gauge records systolic pressure, which is the pressure of the blood flow when the heart beats, and diastolic pressure or the pressure between heartbeats. The problem with the sphygmomanometer is that peripheral blood pressure can vary from 'core', or 'central' blood pressure.

Hence Atcor's SphygmoCor represents a novel advance in assessing cardiovascular diseases. Several studies have been conducted that support the clinical benefit of the SphygmoCor device and approach to measuring central blood pressures. One of these studies, the Conduit Artery Functional Evaluation (CAFE) study demonstrated that large differences existed between central and brachial (peripheral) blood pressures. The study showed certain drugs that controlled blood pressure delivered significantly different outcomes at the heart versus at the bodies' extremities.

**Distribution approach**

At this stage of its development, Atcor's business is focused heavily towards building sales directly in the US, with a second line emphasis on Europe. The company's initial sales have been gained in the research and pharmaceutical industry market. This is the smallest of the three markets targeted by Atcor. The next step is to focus on the academic specialist clinics, a market the company estimates to be worth in the order of $US250 million. Although generating sales in this market is important, the endorsement of the Atcor technology that could be provided by specialists would be critical to the more widespread uptake of the technology in the specialist primary care market, a market the company estimates to be worth US$670 million. Accessing this market will require the establishment of a marketing partner.

The company recently installed a US based President and CEO, Duncan Ross, to direct the company's operations. Twelve staff are now based in the US, including Vice President positions for Reimbursement and Payers, Marketing Development, Scientific and a Director of Marketing. Also in the US are three sales staff and two application engineers. Although this sales and marketing force is an expensive cost for a small Australian company, it is a necessary cost if the firm intends to successfully sell its technology into the US in the establishment phase of its sales plan.

**Revenue growth**

Sales for FY2006 were $3.3 million, only slightly higher than the $3.1 million recorded in the previous financial year. The company announced in August that a pharmaceutical company had placed an order for clinical trial services utilising the SphygmoCor technology worth $US1.48 million over the life of the contract, with US$1.1 million recognised in FY2007. The company expects sales to more than double in FY2007. Profitability is not anticipated for that reporting period.

However, the company's sales and marketing expenses are expected to also increase in FY2007. We estimate Atcor's sales and marketing expenses will be in the vicinity of $6 million in FY2007. Assuming the company does double sales for FY2007, then the company's cash position by the end of FY2007, is likely to be closer to $6 million. We expect FY2008 to the year in which Atcor's investemnt in its US sales force yields strong revenue growth.

**Intellectual property position**

Atcor has several patents covering the SphygmoCor technology granted in the US, including patents 6,010,437 and 5,882,311. The company has a licence to US patent 5,265,011 for US territories. Atcor also has several more patents pending in various jurisdiction, including the US.

**The Tipping Point**

An event more likely than others to boost sales for Atcor Medical is when the CPT reimbursement code (93922) for the company's SphygmoCor device receives endorsement from national US bodies of associations of cardiovascular or vascular surgeons. Such national endorsements would facilitate the acceptance beyond a select number of US local or state healthcare authorities and health insurance providers who support the use of SphygmoCor device for testing blood pressure. This would also precipitate entry into the primary care market. The company has also engaged a Washington lobbyist to support this and other marketing goals.

Atcor is capitalised at $18.5 million. At June 30, the company was holding cash at hand of $11.8 million.

*Bioshares* recommendation: **Speculative Buy Class B**

**Summary**

These three companies share a number of features:

- they are single technology focused companies;
- they have products that are in the market;
- they have potential to generate profits within a reasonable time frame;
- they have particular focus on customers in North America;
- the product or combination product and service they sell is a functional replacement for, or improvement over an existing technology; and
- these products essentially generate previously unobtainable information about patients' health status in a non invasive way (Atcor) or collect information more conveniently and create data that can be analysed at a deeper level quickly and cheaply (Brainz and Cogstate).

A long term driver for both Atcor and Cogstate will be the increase in demand for post marketing surveillance of new and existing medicines. These two companies' technologies have the potential to become standard risk management tools for drug companies developing medicines that affect the neurological system (Cogstate) and the cardiovascular systems (Atcor).

Bioshares

# *Alchemia Resumes Control of Synthetic Heparin*

Alchemia moved towards resolving a major commercial impediment this week. It had reached an in principle agreement with its partner **Abraxis Biosciences** to terminate their agreement with respect to the sale and distribution of Alchemia's synthetic heparin. This was a significant step forward for the company in light of recent uncertainties that had developed regarding this program.

The agreement now allows Alchemia to progress to the commercialisation of this product and has averted a stalemate that had seemingly left Alchemia exposed. Alchemia plans to file its ANDA with the FDA independently by mid 2007, six months behind the original anticipated filing date. In the meantime, Alchemia will seek a new marketing partner for the US.

The development comes with some further positive news from the company. **IMS Health** sales data for Arixtra has been acquired by Alchemia. It shows that Arixtra sales in the US are delivering consistent growth since GSK acquired the product in 2004, and are not flat, as recent quarterly data from **GlaxoSmithKline** would suggest. The data that GSK publishes in its quarterly accounts showed that its sales of Arixtra in the US had fallen in the second quarter in the US to US$11 million from US$12 million in the previous quarter. The GSK figures are net sales, which includes discounting by the company.

IMS data released by Alchemia shows that US sales in the second quarter of this year have increased from US$14.45 million in the first quarter of 2007 to US$16.7 million.

The fall in net sales for GSK indicates it is marketing the drug more aggressively in the US. Current growth rates indicate US Arixtra sales could exceed US$150 million by mid 2008, which is the earliest expected approval of Alchemia's generic version of Arixtra.

This does not take into account the expected increase in Arixtra sales once the product is approved for Acute Coronary Syndrome (ACS), which constitutes 30% of the heparin market. Arixtra has shown a clear advantage over rival drug Lovenox, from **SanofiAventis**.. GSK is expected to receive ACS approval by the beginning of 2008. The ACS market in the US for heparin products is estimated at US$500 million a year.

The risk profile of this stock has increased with Alchemia now required to find a marketing partner in the US. The size and quality of the marketing partner in the US, together with the type of agreement that can be made and the time taken to find a partner to sell Arixtra will reflect the inherent value of this commercial asset that Alchemia has developed.

In other developments for Alchemia, Ian Nisbet, the former CEO of **Meditech Research**, which has been acquired by Alchemia, announced he was leaving the company. This was a disappointing decision for Alchemia, given his extensive experience in oncology drug development. However, it was not altogether unexpected following the merger of the two companies. Alchemia's ability to progress the clinical program inherited from Meditech Research have been hampered until a replacement has been secured.

Alchemia is capitalised at $92 million with $26 million in cash at the end of June this year.

*Bioshares* recommendation: **Speculative Buy Class A**

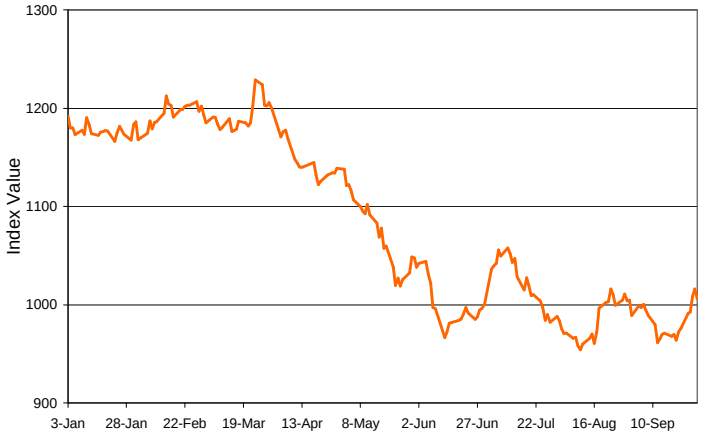
Bioshares

**Bioshares Model Portfolio (29 September 2006)**

| Company | Price (current) | Price added to portfolio |
|---|---|---|
| Acrux | $0.80 | $0.83 |
| Alchemia | $0.65 | $0.67 |
| Avexa | $0.230 | $0.15 |
| Bionomics | $0.17 | $0.210 |
| Biosignal | $0.18 | $0.22 |
| *Cogstate* | $0.20 | $0.20 |
| Cytopia | $0.695 | $0.46 |
| Chemgenex Pharma. | $0.48 | $0.38 |
| Evogenix | $0.460 | $0.47 |
| Optiscan Imaging | $0.450 | $0.35 |
| Mesoblast | $1.180 | $1.27 |
| Neuren Pharmaceuticals | $0.42 | $0.70 |
| *Peptech* | $1.31 | $1.31 |
| Pharmaxis | $2.25 | $1.90 |
| Prima Biomed | $0.059 | $0.09 |
| Sirtex Medical | $2.30 | $1.95 |
| Sunshine Heart | $0.15 | $0.19 |

**Portfolio changes:**
*Peptech and Cogstate have been added to the portfolio*

## *The Bioshares 20 Index*




**The Bioshares 20 Index**
*Change from June 30, 2006* **0.6%**
*Change - week ago* **3.1%**

**Nasdaq Biotech Index**
*Change from June 30, 2006* **1.5%**
*Change - week ago* **2.5%**

## How Bioshares Rates Stocks

For the purpose of valuation, *Bioshares* divides biotech stocks into two categories. The first group are stocks with existing positive cash flows or close to producing positive cash flows. The second group are stocks without near term positive cash flows, history of losses, or at early stages of commercialisation. In this second group, which are essentially speculative propositions, *Bioshares* grades them according to relative risk within that group, to better reflect the very large spread of risk within those stocks.

### Group A

Stocks with existing positive cash flows or close to producing positive cash flows.

| | |
|---|---|
| **Buy** | CMP is 20% < Fair Value |
| **Accumulate** | CMP is 10% < Fair Value |
| **Hold** | Value = CMP |
| **Lighten** | CMP is 10% > Fair Value |
| **Sell** | CMP is 20% > Fair Value |

(CMP–Current Market Price)

### Group B

Stocks without near term positive cash flows, history of losses, or at early stages commercialisation.

***Speculative Buy – Class A***
These stocks will have more than one technology, product or investment in development, with perhaps those same technologies offering multiple opportunities. These features, coupled to the presence of alliances, partnerships and scientific advisory boards, indicate the stock is relative less risky than other biotech stocks.

***Speculative Buy – Class B***
These stocks may have more than one product or opportunity, and may even be close to market. However, they are likely to be lacking in several key areas. For example, their cash position is weak, or management or board may need strengthening.

***Speculative Buy – Class C***
These stocks generally have one product in development and lack many external validation features.

***Speculative Hold – Class A or B or C***

***Sell***

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