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Biosshares

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Edition 342

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

In this edition...

Well what a year for Australian biotech! Three acquisitions of local companies by international groups during the year, and in particular two $300 million plus deals have highlighted the potential value that can be generated from such technologies. Will we see more? The year ahead in 2010 promises to be just as eventful with many late stage companies potentially in play.

In this edition we give our Top 5 mid cap and Top 5 small cap picks for 2010. And on a very relevant issue, Merilyn Sleigh, former CEO of Evogenix, which was acquired by Arana Therapeutics, looks at the impact on the local sector from businesses that have been acquired by larger suitors in recent years.

We wish you a safe and festive season ahead and look forward to assisting you with you investments in 2010!

The Editors

Companies Covered: ACR, ACL, ACG, BDM, BOD, CGS, CXS, MSB, PAB, SPL

	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 (May '07 - May '08)	-36%
Year 8 (May '08 - May '09)	-7.3%
Year 9 (May '09 - Current)	73.7%
Cumulative Gain	**237%**
Av Annual Gain (9 yrs)	**21.2%**

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Stock Picks – 2010

It has been an exceptional year for the Australian biotech sector. In this last edition for 2009, we select our top five mid-cap biotechs (greater that $50 million) and the top five biotech small caps (less than $50 million).

Larger Caps

Acrux (ACR)

Share Price: $2.10
Capitalisation: $337 million

As a stock pick, Acrux may be an early out-performer for 2010 if a major transaction, based on the significant progress of the Axiron product in 2009, is achieved. Axiron is a trandermally delivered product developed for the treatment of testosterone deficiency in males. As a deoderant style product administered under the armpit, Axiron offers an advantage of convenience over other testoterone products, which are gel based and which run the risk of secondanry transfer. The market opportunity is in the order of US$1 billion in North America, and potentially much greater in ROW territories. Phase III studies were completed this year, with the product comfortably exceeding the requirements set by the US FDA.

Recently, the company appointed Credit Suisse to assist with the transactional work. Exactly what type of transaction is in play is not known. Acrux could be aiming to license Axiron to a global partner; alternatively the product could be up for sale or then again the entire company could be on the auction block. We speculate that it is the latter of these three scenarios that is being worked on, assuming that a successful acquiror would be not interested in paying royalties in the 25%-30% range.

Bioshares recommendation: **Speculative Buy Class A**

Starpharma (SPL)

Share Price: $0.64
Capitalisation: $152 million

Starpharma is one company whose share price has come out of 2009 as a stock with real momentum. SPL shares were as low as 16.5 cents in March, and have marched on boldly ever since. The company completed a $15.6 million capital raising in November, in a funding round where demand significantly exceeded supply. **Orbis Funds Management**,

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Publication Dates – Break over Holiday Period

Bioshares is published 48 times per year.
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a Sydney-based invesor with a portfolio of investments in biotech, including **Pharmaxis** and **Acrux** (and until the year, **Peplin**) took up a 7.7 % holding in the stock.

Starpharma's recently announced bacterial vaginosis program with Vivagel is a more than interesting product development opportunity (see *Bioshares* 337), given the significant unmet need in that disease area and fits within a three year outlook.

Of closer term interest for Starpharma in 2010 may be in opening up new areas of application. The company continues to implement new research and collaboration deals for its dendrimer chemistry, the latest being in the agricultural pesticides with an unnamed company. The chances of seeing further agri-chemical collaborations initiated have been flagged by the company, and such events may drive growth in SPL share price. Any price weakness in SPL stock is likely to be met by with keen interest by stock accumulators looking to benefit ahead of anticipated flow of revenue in 2011 from Starpharma's condom coatings product with SSL.

Bioshares recommendation: **Speculative Buy Class A**

Mesoblast (MSB)
Share Price: $1.36
Capitalisation: $189 million

2010 should be a pivotal year for Mesoblast. Results from Phase II trials in several applications, progression to pivotal/Phase III studies in the US and potentially a licensing/partnering deal are the major milestones for the company next year.

In 2009, the company and its investee company Angioblast (of which Mesoblast owns 38.4%) have seen positive results from Phase II studies in treating heart failure, bone marrow transplant (expansion of hematopoietic and progenitor cells using the company's own allogeneic stem cells), and positive preclinical results in new applications. These new applications are for the treatment of intervertebral disc damage and some early results in the potential treatment of diabetes.

The launch of a product in Australia under a Special Access Scheme for the treatment of non-healing bone fractures in 2010, while not being a major revenue earner, will be a very public example of the utility of adult stem cell treatment in a commercial setting. In a 10 patient study, eight of the 10 patients, whose bones had previously not healed for several months, achieved complete union following stem cell implants provided by Mesoblast.

Bioshares recommendation: **Speculative Buy Class A**

Chemgenex Pharmaceuticals (CXS)
Share Price: $0.96
Capitalisation: $272 million

Chemgenex's lead drug candidate, Omapro, for the treatment of chronic myeloid leukemia (CML), is due for market launch in the US in mid 2010, pending FDA approval. Chemgenex has just licensed the European rights to the drug to **Hospira**, with an upfront $17.8 million payment, and a total deal value worth $137 million in the CML area alone. Chemgenex retains full rights to two thirds of the global market for CML.

Initially the drug will target a niche market, but this can be expected to expand, including potentially use in combination with Gleevec when that drug comes off patent. Chemgenex will deliver a complete service to patients with its own sales force, which we suggest may include a tie-up with a diagnostic for the 315I mutation associated with CML. The incidence of mutations continues to grow as patients live longer with treatment under Gleevec.

There are 36 key cancer centers in the US that Chemgenex is likely to initially target in six key geographic regions. The drug will be reviewed by an FDA advisory committee on 10 February next year, with a decision in March likely from the FDA on approval.

Bioshares recommendation: **Speculative Buy Class A**

Alchemia (ACL)
Share Price: $61.5
Capitalisation: $99 million

Alchemia's lead product is awaiting approval from the FDA. That product is a generic version of a synthetic heparin product, Arixtra (fondaparinux), which currently generates sales of US$200 million a year in the US. Alchemia's partner, Dr Reddy's, should be able to capture at least 40% of that market reasonably quickly. We estimate that will deliver a profit to Alchemia in excess of $30 million a year from the US alone at current sales volumes of the drug.

Alchemia CEO Pete Smith recently said that fondaparinux has the potential to build Achemia into a $2 stock. However the company's other program with HA-irinotecan (and the HyACT platform which combines hyaluronic acid with existing cancer drugs) has the potential to build Alchemia into a $10 stock.

Once Alchemia's fondaparinux is approved, Alchemia will start a 330 patient Phase III trial with HA-irinotecan. This trial will take around two years to complete. The good news is that only one trial will be required for US approval, and the primary endpoint will be progression-free survival, which is quicker to show efficacy than overall survival.

Bioshares recommendation: **Speculative Buy Class A**

Smaller Caps
Atcor
Share Price: $0.195
Capitalisation: $20 million

Data supporting the measurement of central blood pressure continues unabated and in turn this bolsters the prospects for Atcor's Sphygmocor system which can be used to non-invasively make that measurement.

A recently published five year NIH study of 2,405 people followed for 5.6 years found that when central pulse pressure exceeded 50 mg Hg, as measured by Atcor's Sphygmocor system, the risk of cardiovascular events increased sharply. In contrast, no predictive relationship could be established when the traditional measurement at the cuff was used. This is a major supportive finding in favour for Atcor's technology.

Atcor has been consistent and focussed company to date. The company has managed to lock in revenues from pharmaceutical companies that use the Sphygmocor system in clinical trials. This has put the company on a solid footing. The company expects double digit growth in sales to continue.

The company is working to receive a CPT 1 reimbursement code in the US, which is still some time away. However, what really works in favour of companies seeking reimbursment is strong and mounting evidence in favour of a technology. This is very much the situation that Atcor finds itself in, in the most positive sense.

Bioshares recommendation: **Speculative Buy Class A**

Patrys

Share Price: $0.135
Capitalisation: $25 million

Patrys is a pick from an 'out of favour' class of companies, that of the early stage drug developers. If Patrys is like most other drug developers, it will be looking to raise funds in the next twenty four months. However, the company is one to watch because it is developing antibody drugs against which there are no other second generation antibody drugs being developed. In other words it is developing antibody drugs in uncontested territory, and Patrys has the potential to block other companies' attempts to also drug these targets.

Patrys is on the way to launching its lead anti-cancer antibody PAT-SM6 in a clinical trial in 2010 H1, having developed the necessary manufacturing processes and yields for the compound. This will be an major step for the company because Phase I cancer studies with antibody drugs can deliver drug activity data These trials can also often be linked or bridged to Phase II studies as dosing information comes to hand. The upshot is that value inflection points can be determined much earlier for antibody drugs compared to small molecule drugs.

PAT-SM6's entry into the clinic will be followed in H2 2010 by PAT-LM1, another anticancer antibody which targets the nmt55 receptor. 2010 will be a big year for Patrys.

Bioshares recommendation: **Speculative Buy Class B**

Biodiem

Share Price: $0.165
Capitalisation: $12.6 million

Biodiem's core asset is being quietly commercialised, now through **Merck** after Merck's acquisition of **Schering Plough** this year. The asset is a live attenuated influenza vaccine. The first Phase I trial in 117 volunteers has been completed successfully. In October this year a second Phase I trial was started in 140 volunteers over the age of 50. The trial will look at the safety, tolerability and immune response. The immune response in the older population will be a key parameter to be measured, with other flu vaccines less effective in the elderly.

As this program progresses, one unresolved issue is the North American rights to the vaccine which reside with Biodiem. As the program progresses and if it is successful, the North American rights will become more valuable. This could result in a significant milestone payment to Biodiem in the next 12 months. This and results from vaccine trials, both for seasonal flu and pandemic flu, will be key drivers for this stock in 2010. Biodiem had $2.7 million in cash at the end of October.

Bioshares recommendation: **Speculative Buy Class C**

Cogstate

Share Price: $0.315
Capitalisation: $21 million

Over the last three years, Cogstate has been formed into a profitable business with a strong and consistent growth rate. The company is expected to generate sales for calendar year 2009 of over $9 million and we estimate the company will generate a pretax operating profit of around $2 million for this financial year.

The stock offers entry into what is now an established and profitable business. Growth from the business will come from an expanding market size in cognitive testing for new drug trials, and improved branding of the product, and eventually a move into larger Phase III trials. Applications of the technology into other markets also remains a potential.

Cogstate offers an excellent medium and long term investment opportunity.

Bioshares recommendation: **Buy**

Cont'd on page 5

Correction
In Bioshares 339 in our commentary on Alchemia, we incorrectly stated that GlaxoSmithKline will be seeking approval for ACS in Europe for Arixtra. In fact ACS approval in Europe has already been received and GSK is now seeking ACS approval in the US. Of the 130 ANDAs filed by Alchemia's partner Dr Reddy's with the FDA, it should be noted that many are still pending approval according to Alchemia.

*And the sentence: "Historically when **HA** has been combined with Erbitux, which is very expensive and has side effects, PFS is extended out to only around four months" should be replaced with: "Historically when **irinotecan** has been combined with Erbitux, which is very expensive and has side effects, PFS is extended out to only around four months".*

Contributed Commentary

Where Are They Now – What Happens When Australian Biotechs Are Acquired?

By Dr Merilyn Sleigh

2009 has been a bumper year for M&A activity in the biotech sector internationally, as pharma companies and cashed up, longer-established biotechs take advantage of GFC-induced pressures on smaller companies to expand their capabilities and pipelines. Australia has also been a target for international acquisitions, with the **Arana** takeover by US company **Cephalon**, **Leo Pharma's** acquisition of **Peplin** and **Cytopia's** merger with **YM Pharmaceuticals** as notable examples.

Are such acquisitions a good or a bad thing for the Australian biotech sector? Certainly it is a positive recognition of the competitive value of the technology and products of our companies, a sign of a coming-of-age in the sector locally, and in some instances and for some shareholders, an attractive exit mechanism. But if the outcome is the loss of investment, R&D, manufacturing and strategic and business capabilities from the sector, then it is not a good result for development of Australian biotech over the longer term.

It is too early to determine the outcomes for the targets of 2009 transactions. But a look back at previous examples of Australian companies acquired tells a story that is mixed, but with some encouraging aspects.

There have been many M&A transactions between Australian companies over the past 5 years, and a surprising number of overseas acquisitions by Australian biotechs . However, in the same period, the number of listed Australian companies going to overseas owners has amounted to just 6, with the Cytopia deal still pending[1].

GroPep was an Adelaide-based company which had a profitable business based on a catalogue of locally manufactured high value, specialised research reagents, particularly around insulin-like growth factors. Although conducting an R&D program focusing on newer biological agents for clinical applications, GroPep was largely valued by the market on the basis of its product sales. It was acquired by **Novozymes AS**, in 2006.

Today, GroPep remains on its original site as an active operating division named **Novozymes GroPep**. It has a catalogue of 100 products which it continues to sell into the research market. GroPep also provides R&D and bulk biologicals, supplied through **Novozymes Biopharma**, a separately listed company providing reagents, technology and services to the biopharmaceutical industry. The therapeutics aspect of the business, and some management staff, appear to have disappeared.

Bresagen, also Adelaide-based and ASX-listed, was acquired by **Hospira** in 2006. Bresagen was utilising proprietary technology for efficient biologicals production in bacterial systems, both for its own products under development, and for third parties. It was an early entrant into biogenerics, a particular focus of Hospira. Bresagen also had a US-based foray into gene therapy.

Today, under the umbrella of Hospira, the original Bresagen site continues to operate as a contract manufacturer for external parties, and together with the former Mayne Pharma in Melbourne, as one of Hospira's regional nodes, providing both specialised manufacturing and Australian regulatory expertise. Gene therapy and own-product oriented R&D no longer appear to be a part of the operations.

A third transaction completed in late 2007, that of Brisbane-based **PanBio**, was by US diagnostics company **Inverness Medical Innovations Inc**, which was at the time engaged in rapid expansion of its range of products via a series of acquisitions. Panbio had successfully developed, manufactured and was marketing a range of diagnostics for infectious disease, including infections of particular significance in tropical regions.

PanBio is now branded as **Inverness Medical Innovations Australia**. It continues active R&D into delivering new products for locally relevant infections such as dengue fever, and acts as the focus for regional marketing of an expanded range of products including its original catalogue, as well as Inverness products.

The only other listed company acquisitions completed since 2004 are recent examples – **Stem Cell Sciences** by **Stem Cells Inc** (April 2009), the Arana takeover by Cephalon (completed in Q2 2009) and the Leo-Peplin transaction, recently finalised.

In the first case, all Australian activity has been lost, with Stem Cell Sciences operating as a UK-based division of its acquirer and manufacturing a range of human cells and stem cells for application to drug discovery, a continuation of the revenue-generating aspect of its former business.

Arana brings a new capability to Cephalon, which has no products in the biopharmaceuticals area. Initial indications are that R&D into biologicals (mainly antibodies), directed at generating new therapeutic products, will continue in Australia, although local business development activities have been an early casualty of the deal.

With Peplin both increasingly US-focused and with a single late stage product, it will be surprising (despite a recent Leo Pharma statement) if significant Australian activity continues over the longer term.

Each of the six acquisitions of listed companies appears to be motivated by the chance to access unique capabilities, products and technologies. The acquirors have in most cases been happy to maintain these assets by supporting continuing local activities, although with an increased focus on generation of products and

Cont'd over

[1] *Data from biotechnology Business Indicators, a quarterly review of the industry in Australia by the Australian Government Department of Innovation, Industry, Science and Research www.innovation.gov.au*

– Sleigh cont'd

offering of services linked to immediate revenue generation. The existing activity is an encouraging and perhaps somewhat surprising finding, with Australian staff continuing to acquire valuable skills which may be usefully applied elsewhere in the local biotech sector in the future. What has been lost is research and product development targeted at longer term, high value therapeutics, and associated clinical and business development activities, a disappointing outcome for the ongoing maturation of the sector locally.

With the Peplin product in Phase III and already managed from the US, the Arana Cephalon deal will be the one to watch over the next year or two to see if this mixed outcome can be improved. Whether Australia can maintain its role as the pre-eminent division for biologicals discovery and early development within the wider Cephalon company remains to be seen, as will the extent to which the local group participates, and involves Australian advisers and contractors, in the full program of development of successful therapeutics.

Merilyn Sleigh has been a long term participant in the Australian biotech industry, currently serving as a director of Tyrian Diagnostics Ltd and Clover Corporation Ltd, and an advisor to biotech companies and their investors.

Bioshares

– Stock Picks cont'd

BioMD

Share Price: $0.063
Capitalisation: $5.4 million

BioMD is a microcap biotech stock. Its core proprietary technology, called ADAPT, is used to process bovine pericardium tissue that can be used in human tissue implants. BioMD has completed a trial in 30 children repairing heart deformities. The appeal of the technology is that it provides tissue that is not recognised by the immune system, but unlike polypropylene meshes, it does not become fibrotic and does not shrink.

The company is currently conducting a 20 patient study in Sydney in pelvic floor reconstruction. The market global market for this indication is estimated to reach US$1.5 billion by 2011. Other applications of the technology include for use in tissue heart valves and plastic surgery.

If the Sydney trial is successful, the company will seek to have the product filed for approval in 2010. BioMD is capitalised at only $5.4 million. Its challenge is also funding the commercialization of its technology. However, success in a second clinical trial should see considerable more interest in this stock from investors and potential partners. The company's products could become available to surgeons next year under a Special Access Scheme in Australia.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares

Bioshares Model Portfolio (17 December 2009)

Company	Price (current)	Price added to portfolio	Date added
Biodiem	$0.17	$0.15	October 2009
QRxPharma	$0.82	$0.25	December 2008
Hexima	$0.48	$0.60	October 2008
Atcor Medical	$0.20	$0.10	October 2008
CathRx	$0.62	$0.70	October 2008
Impedimed	$0.78	$0.70	August 2008
Mesoblast	$1.37	$1.25	August 2008
Circadian Technologies	$0.65	$1.03	February 2008
Patrys	$0.14	$0.50	December 2007
Bionomics	$0.37	$0.42	December 2007
Cogstate	$0.32	$0.13	November 2007
Sirtex Medical	$6.87	$3.90	October 2007
Clinuvel Pharmaceuticals	$0.28	$0.66	September 2007
Starpharma Holdings	$0.64	$0.37	August 2007
Pharmaxis	$2.78	$3.15	August 2007
Universal Biosensors	$1.75	$1.23	June 2007
Probiotec	$2.45	$1.12	February 2007
Chemgenex Pharma.	$0.96	$0.38	June 2006
Acrux	$2.10	$0.83	November 2004
Alchemia	$0.62	$0.67	May 2004

Portfolio Changes – 17 December 2009

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: Pharmaxis, Cytopia, Starpharma Holdings, Cogstate, Bionomics, ChemGenex Pharmaceuticals, Circadian Technologies, Biota Holdings, Halcygen Pharmaceuticals, Peplin, Impedimed, QRxPharma, Patrys, Labtech Systems, Hexima, Tyrian Diagnostics, Mesoblast, Atcor Medical, CathRx, BioMd

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