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In this edition...
After two years in the doldrums, if share prices are the yardstick, the biotech sector in Australia is about to reach a defining moment. Half year results to be reported in February should illustrate the resilient nature of thart part of the healthcare sector where companies generate sales. And value for progressing late stage programs looks to be finally be rewarded if Peplin is any example in the early part of the new year.
For many others, it will be time to restructure, reassess or hibernate until financial condistions improve and sentiment to this sector turns around.

The Editors
Companies Covered: ACG, ACL, CUV, NEU, PLI, QRX

	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 - current)	-35%
Cumulative Gain	**35%**
Av Annual Gain (7 yrs)	**17.8%**

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Bioshares

23 January 2009
Edition 296

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

A Few Positives Launch Biotech Into 2009

The new year in 2009 has started as predicted in late 2008: the leading companies in the sector will continue to make strong progress; cash flow generating businesses will largely exhibit the outputs that are characteristic of the more resilient healthcare sector; and microcap cash-burning biotechs will be forced to dramatically rethink their businesses plans in response to the ongoing funding crisis.

What is perhaps unexpected is an upturn in interest from investors in Australian biotech stocks in the first few weels of 2009. Following positive Phase II trial results, Peplin has seen its share price increase by 110% from last month. Alchemia's share price doubled following a surprise milestone payment from its partner Dr Reddy's although has retraced some of that ground. And even microcap biotech Tissue Therapies has seen its share price increase by over 200% from its low in December following positive results from its Australian wound treatment trial.

Atcor Medical – Higher Sales Growth Anticipated

Atcor Medical released its quarterly cash flow statement and has upgraded its full year sales forecast for this financial year. For the first six months of this financial year, the company generated $4.7 million in receipts from customers with sales of $5.4 million (up 76%) recorded for the period. Net cash outflow was just under $1.2 million. The company had $2.9 million in cash at the end of the quarter and does not anticipate raising further funds in the 'foreseeable future'.

For the most recent quarter, cash outflow increased to $1.0 million although receivables increased by $1.2 million over this period. The lower Australian dollar has had a positive impact on sales (up 64% in constant dollar terms) however this will be limited on the company's bottom line result with a substantial proportion of its costs being offshore.

To reach profitability we estimate the company will need to generate sales of between $13 – $14 million. At current growth rates, we estimate this should occur towards the end of 2009.

Atcor is pioneering, promoting and selling a non-invasive technology for the measurement of central blood pressure. Measurement of central blood pressure together with the standard cuff pressure allows the elasticity or stiffness of the arteries to be accurately measured. In the last three years, three major studies involving in excess of 15,000 people have confirmed the importance of measuring central blood pressure in predicting cardiovascular disease.

Bioshares Thredbo Biotech Summit Dates
28 – 29 August, 2009

Registration for this year's conference will open in March

Atcor generates around 50% of its revenue from the use of its diagnostic in clinical trials by pharmaceutical companies. Measuring central blood pressure in clinical trials has the potential to give products marketing distinction and is expected to be received well by regulators following deaths from cardiovascular deaths using the COX-2 inhibitor drugs such as Vioxx, which caused an estimated 90,000 – 140,000 heart attacks.

Atcor sells its products directly in the US and through distributors in other regions. The company also sells its product into research institutions. An accelerated adoption is expected once the technology is utilised by specialist and primary care doctors.

ACG: 18 cents

Cash position (31/12/08)	$2.9 million
Market capitalization	$18 million
Bioshares recommendation	Speculative Buy Class A

Half year results to be reported next month will be important to monitor for a number of companies in the sector (see table below, which excludes large caps). Not only do we expect strong growth to continue with most customers largely unaffected by the global economic slowdowns (a welcome feature of the healthcare sector), but positive currency movements (a lower Australian dollar) should boost top and bottom line results.

Strong HY results expected from established businesses

Company	Comments
Atcor Medical	76% increase in first half sales (unaudited) to $5.4 million
Probiotec	Strong profit growth to continue from all business units, in excess of 20% growth over pcp
Cellestis	Very strong profit growth anticipated with help of positive currency movements
Sirtex Medical	Strong sales growth of 28% and may accelerate. Non-discretionary spending market (oncology). Strong benefit from low AUD.
IDT	Contracts generated in AUD. Profit growth to continue but affected by slowdown in biotech sector
Cogstate	Maiden profit result expected

Emerging life science company sales to monitor in 2009

Company	Comments
Universal Biosensors	Strong sales (up to $30 million) to commence in 2009
CathRx	Sales expected to ramp up in 2H 2009
Nanosonics	Sales expected to ramp up in 2H 2009
Acrux	Accelerated Evamist royalties anticipated in FY2010
Labtech Systems	Royalties from Previ-Isola consumables to commence in 2009 from Biomerieux
Tyrian Diagnostics	Orders of first WheatRite test from Bayer received

Peplin Sailing Through Final Stages of DrugTrials

Peplin is sailing through the final stages of the clinical development of its drug candidate, PEP005, for the treatment of non-melanoma skin cancers, and in the first instance, pre-cancerous skin lesions called actinic keratosis (AK). It has started a 240 patient Phase III trial for the treatment of AKs on the body (not head and neck) and expects to report results in the first half of this year. The company recently completed a Phase II dose ranging study on the head and neck with positive results and expects to launch a Phase III study for treatment of AKs on the head this year following an end of Phase II meeting with the FDA.

These two trials should be sufficient for the company to file the drug for approval in the US– we estimate in around 12 months time – to get the drug on the market in the US in 2011.

The Phase II study recently reported on, tested PEP005 in 240 patients in eight groups for the treatment of AKs *over a two or three day treatment period only*. The results confirmed the dose response of the drug at higher levels, which is a very satisfying result, with a complete clearance rate of 42.3% achieved in the highest group. Competing topical products on the market have complete clearance rates of between 40%-50% (for Aldara, Carac, Efudex and Solaraze). However these products need to be used daily or twice daily for at least four weeks, or in the case of Aldara, twice a week for 16 weeks.

These comparable efficacy results are the peak results. In practice this is not achieved because of the high demand to continue treatment for four weeks or longer. By comparison, the PEP005 results were achieved for only two or three applications. This is the key appeal of the Peplin drug. The side effect profile of PEP005 would also appear to provide an advantage over existing treatments. Existing treatments sell for between US$750 per treatment course (Aldara) to US$150 for Carac.

Peplin has sufficient funds to complete its Phase III studies. The enrollment and treatment time for the studies is short and we expect the company will meet the above stated timelines, unless additional studies to those specified, are required by the FDA. The first Phase III study for treatment of AKs that are not situated on the head has been completed. This program is being conducted under a Special Protocol Assessment with the FDA, which reduces the risk that additional data will be requested to approve the drug.

PLI: 60 cents

Cash position (31/12/08)	US$33.8 million
Market capitalization	$181 million
Bioshares recommendation	Speculative Buy Class A

Clinuvel Pharmaceuticals Reports Positive Interim Phase III results

Clinuvel Pharmaceuticals is another dermatology focused biotech company that is progressing well through its final Phase III stage of development. The company this week reported interim results from its lead Phase III trial in the treatment of EPP (erythropoietic protoporphyria), which is a severe sun intolerance of the skin.

Cont'd over

This first use of this drug candidate is a niche application, with only about 200 sufferers of this condition in Australia. Orphan drug status was granted in Europe and the US in 2008. Selection of a niche indication is a valid approach for the company to get the drug on the market as quickly as possible and then to expand the application into other conditions, of which four others have so far been identified by the company, with trials underway. We estimate there are around 4000 people affected by EPP in major markets.

The targeting of niche applications should not be undervalued by investors. Clinivel is seeking to follow a development plan similar to that adopted by the very successful **Genzyme,** which also targeted niche applications. Genzymes's Ceredase, which is designated for the treatment of the few thousand people with Gaucher disease in the US, was released in 1991 and generated sales of US$1.1 billion in 2007, or one third of that company's total revenue stream.

Interim trial results

The current Phase III trial for EPP involves 101 patients in Europe and Australia treated for 12 months. Interim results were released from the first 14 patients because of the request from these patients to continue treatment under compassionate use following their participation in the trial and to understand the whether the drug is having an effect. There will be no further interim results from this trial.

The drug candidate, named afamelanotide, is designed to increase the level of skin pigmentation by increasing natural melanin density, thereby replicating the natural defense that people with darker skin have against the ultraviolet radiation from the sun. In this result in only 14 people, there was a statistically significant increase in skin darkening ($p=0.048$) – a p-value (probability) greater that 0.05 is not considered statistically significant. The differences in the number of phototoxic reactions between the placebo and the active group was not statistically significant although larger trial numbers will help in achieving this one of two primary endpoints.

What was statistically significant was the differences in total severity of phototoxic reactions ($p=0.028$) and the maximum severity of reactions ($p<0.001$) with a mean value of severity of reactions the other primary endpoint. The safety aspect of the drug continues to be good.

Largest market application – Organ transplant patients

The largest application identified to date for the Clinuvel drug candidate is for the prevention of skin cancers in organ transplant recipients who are on continued immune suppression treatment. These patients have a much higher chance of developing skin cancers that anyone else because of the constant suppression immune system.

There is now a significant demand for even prosthetic ears for these patients (technical jargon 'renal ears') for kidney transplant patients because of this high susceptibility to skin cancer development on the body, particularly the ears. Kidney transplant recipients are currently checked every three months for skin cancer damage at three to five years after treatment. There are an estimated 1000-2000 people in Australia alone on auto-immune suppression treatment.

Whilst this is clearly the largest application, to prove this indication will require several years of treatment and follow-up.

Clinuvel is awaiting approval to commence its studies in the US having filed an IND last month. It is anticipated the current EPP study will be completed by the end of the year, with results out as early as October, and with the product to be filed for approval in late 2009 or early 2010 in Europe.

CUV: 25 cents

Cash position (30/9/08)	$46 million
Market capitalization	$76 million
Bioshares recommendation	Speculative Buy Class A

QRxPharma – Another High Level Appointment

One of the investment options that is being missed at the moment is that of QRxPharma. The stock is still trading at a significant discount (although is thinly traded) to its cash backing (37%) and this week announced another high profile management appointment. Dr Jesus Soriano was appointed as Executive Vice President.

Soriano was previously the Senior Director of Business Development with **Osiris Therapeutics**. *Bioshares* readers will be familiar with Osiris, which is a comparator adult stem cell company to Mesoblast. In November (see edition *Bioshares* 288), Osiris struck a US$1.4 billion deal with Genzyme, including a US$130 million upfront fee. Soriano was the driver of that deal and will be extremely useful to QRxPharma which is currently in business development discussions with potential marketing partners for its novel opioid combination program, which is at the Phase III stage of development.

QRX: 25 cents

Cash position (30/9/08)	$29.9 million
Market capitalization	$19 million
Bioshares recommendation	Speculative Buy Class A

Alchemia – Partner Edges Closer to ANDA Submission

Alchemia surprised the market late last year with a US$1 million milestone payment from its marketing and manufacturing partner, **Dr Reddy's**. Dr Reddy's will market and manufacture a generic version of Arixtra, called fondaparinux. A further payment of US$625,000 is expected by year's end.

The reason for the milestone payment was not disclosed. We anticipate Dr Reddy's will file this first generic for Arixtra for approval with the FDA in this quarter. We expect the drug will be on the market in the US by the end of 2009 if the FDA approves the drug within a six month timeframe, which is the expectation for first generics. In 2008, Arixtra generated sales of US$172 million for GlaxoSmithKline, up 67% over 2007. At current sales, Alchemia

stands to generate a profit share in the order of $30 million a year based on assumptions previously stated.

It will seem like a long wait for Alchemia shareholders since the company listed in 2003. However it was originally anticipated that the drug would reach the market in 2008 (as stated in the company prospectus). An 18 month delay in manufacturing and bringing to market one of the most difficult drugs to make may be viewed as a reasonable achievement, particularly when revenues flow and the expected profit share is given full effect.

ACL: 12 cents

Cash position (Sept 2008)	$12.3 million
Market capitalization	$20 million
Bioshares recommendation	Speculative Buy Class B

Neuren Plans for Restructure

Phase III trials do not always go as planned, particularly in hard to treat areas such as prevention of cognitive damage or decline. Neuren's Phase III trial with Glypromate failed, with the trial not helped by the low level of cognitive decline seen across the whole patient group in the trial.

Given the difficulty in raising funds needed to continue the company's programs, Neuren plans to restructure its assets. This includes placing its now lead asset NNZ-2566 for the treatment of traumatic brain injury into a US-subsidiary into which private equity could invest and US Army funding to be partitioned for this program. Early stage cancer programs will likely be placed in a joint venture majority owned by Neuren with a NZ$1.1 million investment by a New Zealand-based trust. Other assets, including Motiva will be licensed out or co-development relationships established.

NEU: 0.8 cents

Cash position (30/9/08)	NZ$4 million
Market capitalization	$2 million
Bioshares recommendation	Avoid

Bioshares

Bioshares Model Portfolio (23 January 2009)

Company	Price (current)	Price added to portfolio	Date added
ASDM	$0.40	$0.30	December 2008
QRxPharma	$0.25	$0.25	December 2008
Hexima	$0.27	$0.60	October 2008
Atcor Medical	$0.18	$0.10	October 2008
CathRx	$0.54	$0.70	October 2008
Impedimed	$0.66	$0.70	August 2008
Mesoblast	$0.80	$1.25	August 2008
Cellestis	$1.60	$2.27	April 2008
IDT	$1.65	$1.90	March 2008
Circadian Technologies	$0.61	$1.03	February 2008
Patrys	$0.07	$0.50	December 2007
Bionomics	$0.20	$0.42	December 2007
Cogstate	$0.15	$0.13	November 2007
Sirtex Medical	$1.70	$3.90	October 2007
Clinuvel Pharmaceuticals	$0.25	$0.66	September 2007
Starpharma Holdings	$0.18	$0.37	August 2007
Pharmaxis	$1.55	$3.15	August 2007
Universal Biosensors	$0.63	$1.23	June 2007
Biota Holdings	$0.43	$1.55	March 2007
Probiotec	$1.42	$1.12	February 2007
Peplin Inc	$0.60	$0.83	January 2007
Arana Therapeutics	$0.87	$1.31	October 2006
Chemgenex Pharma.	$0.43	$0.38	June 2006
Cytopia	$0.13	$0.46	June 2005
Acrux	$0.57	$0.83	November 2004
Alchemia	$0.12	$0.67	May 2004

Portfolio Changes – 23 Jan 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

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