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Biosharesv

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

In this edition...
If you didn't hear the sound of a crashing stockmarket on Friday, you will know about it soon enough as single digit performance returns to most industry sectors. The exception may be healthcare, which offers a number of safe haven stocks, led by CSL, Cochlear, Resmed and Sigma Pharmaceuticals.

But the attractiveness of quality biotechs might get a boost in the near term if the worlds top pharma and device companies decide to go shopping for new products and projects. The top twenty companies with US listings hold more than US$130 billion in cash and cash investments. Pfizer alone holds US$25 billion. We expect that an aggressive round of take-overs will commence soon, starting with companies with weakened cash positions but with attractive products in development.

Companies covered: ACG, HGN, IPD

	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)	-28.5%
Cumulative Gain	**49%**
Av Annual Gain (7 yrs)	**17.8%**

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Safe Haven Stocks in the Life Sciences Sector

The ASX Healthcare Index fell 5.2% on Friday, but less than the 8.2% loss recorded for the All Ords, on what may be seen as a Black Friday event for global equity markets. However, investors have been gravitating to large cap healthcare and pharma for some time and a desire by some investors to convert holdings in **CSL**, **Resmed**, **Cochlear** and **Sigma Pharmaceuticals** into cash on a day of extreme volatility was to be expected.

However, for both the short term (while authorities wrestle with the restoration of liquidity in the world's banking system) and the medium term (as the economies of many countries fall into inevitable recession), life science stocks that represent profitable, mature businesses, with lower levels of gearing, will represent a safe haven for investors.

The stocks of healthcare and pharmaceutical companies are defensive plays because the demand for medicines and medical services is generally not subject to the same types of falls in discretionary income that is felt by many households in recessionary periods. In the Australian context, governments are major payors of medical and healthcare bills, adding considerable security to the sector overall.

We have selected six sets of companies (see page 3) for investors to monitor over the coming weeks as market conditions stabilise and adjust to downgraded earnings outlooks for many other industry sectors. Our view is that the relative appeal of life science stocks has increased and will continue to do so, although investors must retain a high degree of selectivity regarding investment opportunities. The first of the six sets includes the previously mentioned four large cap stocks. The next group is a list of profitable smaller cap stocks including **Blackmores**, **Cellestis**, **Sirtex Medical**, **IDT Australia**, **Probiotec** and **Clover Corp**.

The third set comprises five biotech stocks with very strong cash resources, enough to carry them through at least four years of operations based on recent spending patterns. Included here is **Pharmaxis**, **Arana Therapeutics**, **Acrux**, **Hexima** and **Circadian Technologies**. The standout offering here is Circadian which is trading at a 44% discount to cash.

The fourth group includes eleven companies that have solid cash resources or have very solid investor support. The example in this case is ChemGenex Pharmaceuticals, which recently raised $12 million in very, very difficult market conditions but was able to call on a committed investor base for support. The fifth group includes six companies that should at least be able to weather the next twelve months reasonably well. The sixth group includes a handful of smaller cap companies that are emerging as sales generating companies on the cusp of profitability, if not profitable already. Although lacking in capital scale to warrant the attention of some investors, they certainly qualify as relatively better investment destinations than many other stocks.

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Employment Opportunities

Safe Haven Stocks in the Life Sciences Sector

Company	Code	Price 10/10/08	Cap ($M)				
Group 1 - Life Science Leaders					**PE Ratio**		
CSL	CSL	$36.65	$22,071		31		
Resmed Inc.	RMD	$5.14	$4,156		27		
Cochlear	COH	$55.00	$3,072		29		
Sigma Pharmaceuticals	SIP	$1.32	$1,138		13		
Group 2 - Profitable Smaller Caps					**PE Ratio**		
Blackmores	BKL	$17.50	$285		15		
Cellestis	CST	$2.08	$200		89		
Sirtex Medical	SRX	$1.90	$106		88		
Institute of Drug Technology	IDT	$1.76	$76		11		
Probiotec	PBP	$1.26	$61		10		
Clovercorp	CLV	$0.18	$30		11		
Group 3 - Speculative Biotech - Exceptional Cash Resources				**Cash ($M)**	**S.I. ****		**EV($M)**
Pharmaxis	PXS	$1.90	$370	$112	5.9		$258
Arana Therapeutics	AAH	$0.84	$197	$182	NA		$15
Acrux	ACR	$0.70	$112	$34	11.2		$77
Hexima	HXL	$0.60	$45	$36	5.9		$9
Circadian Technologies	CIR	$0.66	$26	$46	4.6	est	-$20
Group 4 - Speculative Biotech - Solid Cash Resources or Investor Base					**S.I.**		
ChemGenex Pharmaceuticals	CXS	$0.59	$141	$23	1.4	est	$118
Universal Biosensors	UBI	$0.69	$108	$36	2.8		$73
Mesoblast	MSB	$0.83	$99	$14	2.7		$85
Peplin	PLI	$0.30	$91	$87	2.1	est	$4
Biota	BTA	$0.44	$80	$61	2.0	est	$19
Clinuvel Pharmaceuticals	CUV	$0.21	$64	$26	3.6		$38
Impedimed	IPD	$0.72	$63	$13	1.6	est	$50
Nanosonics	NAN	$0.19	$36	$24	3.4		$12
QRxPharma	QRX	$0.41	$31	$30	2.1		$1
CathRx	CXD	$0.60	$26	$18	1.9		$8
Halcygen	HGN	$0.20	$15	$11	3.7		$4
Group 5 - Speculative Biotech - Reasonable Cash Resources					**S.I.**		
Heartware	HTW	$0.55	$171	$46	3.2		$125
Novogen	NRT	$1.09	$111	$34	1.9	est	$77
Starpharma Holdings	SPL	$0.27	$49	$8	1.4		$41
Patrys	PAB	$0.23	$35	$15	2.0		$20
Alchemia	ACL	$0.18	$29	$16	1.9		$13
Genera Biosystems	GBI	$0.17	$9	$4	2.1		$4
Group 6 - Speculative Emerging Revenue Generators					**S.I.**		
Labtech Systems	LBT	$0.15	$14	$10	NA		$4
Cogstate	CGS	$0.15	$10	$1	1.7		$9
Atcor Medical	ACG	$0.11	$11	$3	0.9		$8
ASDM	AMT	$0.32	$12	$1.5	NA		$10
Brain Resource Corp*	BRC	$0.26	$24	$19	6.6		$5

**cash at Sept 30*

*** SI - Survival Index - refer to Bioshares 274 for definitions. Some companies' SIs have been estimated (est)*

Cash Box Companies							
Progen Pharmaceuticals	PGL	$0.67	$40	$77			-$36
Diversa (formerly Ambri)	DVA	$0.01	$2	$4			-$1

Atcor Medical Approaches Inflexion Point

As the Australian life sciences sector progresses, a number of companies are moving towards viable businesses as their products are filed for approval and gain market share. One of the most recent companies approaching that business inflexion point is Atcor Medical (ACG: 11 cents). In the last financial year, the company increased sales by 47% (in constant currency terms) to $6.4 million. With strong growth in revenue expected to continue, the company should move towards profitability in the next financial year.

Atcor has developed the Sphygmocor device which measures central aortic pressure at the heart non-invasively. This has previously only been achieved invasively with a catheter. This device provides immediate information about the health of the heart and the arteries (measured as arterial stiffness) and has been proven to be a very effective predictor of cardiovascular disease.

There are three levels of adoption that the company is seeking to achieve. The first is for use in research and in clinical trials by pharmaceutical and biotech companies and this represents the source of most of the company's current revenue stream. The second is adoption by specialists, mainly cardiologists and nephrologists (kidney specialists). The final and largest market is use by GPs.

Of the current revenue, about 40% is generated from use in clinical trials. There are about 300 installed units in this market, which sell for around $20,000, although the majority are leased for use in mainly cardiovascular drug trials. The leasing and servicing costs are around $10,000 a year.

Atcor employs a very strict product and service schedule, where additional items are an added cost. Atcor does not assist in conducting the assessment of trial participants. It predominantly supplies the instruments, trains the users, and distills the final data. This clearly defined product offering underpins a tight business discipline that is being well received by its clients.

The potential market size for this first tier of revenue from clinical trials is estimated to be in excess of US$50 million a year, and the company has secured around 5% of this market. The current installed base of 300 units has increased from 150 units just 15 months ago and this revenue stream is expected to maintain strong growth.

One of the factors that highlights the potential of this technology is the booming interest in measuring arterial stiffness as an additional diagnostic for cardiovascular disease. In 2006 and 2007, there were more than 1200 publications in each year that considered arterial stiffness, up from around 500 papers a year in the previous two years.

Major study results over last 2 years

Over the last two years there have been three major studies conducted by independent groups clearly supporting the measurement of central blood pressure in diagnosing cardiovascular disease.

CAFE Study, reported 2006

In 2006, a subset of the Pfizer sponsored ASCOT trial look at 2200 patients with hypertension. The study, called the Conduit Artery Functional Endpoint (CAFE) study, showed that anti-hypertensive drugs had different effects on central blood pressure (at the heart measured non-invasively using the Sphygmocor device) despite having a similar impact on the traditional cuff pressure (peripheral pressure), which explained the different cardiovascular outcomes seen in the ASCOT trial.

Strong Heart Study, reported 2007

An NIH funded study called the Strong Heart Study followed 2400 people with and without atherosclerosis over a four-year period. The study found that, using the Sphygmocor device, measurement of central blood pressure was found to be more predictive of future cardiovascular outcomes than measuring traditional cuff pressure.

Cardiff II Study, reported 2008

Perhaps the most significant study to date was reported only recently. This independent study looked at a randomised group of 10,613 people to directly assess the impact of measuring central pressure on identifying elevated cardiovascular risk. The main outcome of this study, was that 70% of patients with high-normal systolic cuff pressure (130-139 mmHg, pre-hypertension) were in fact found to have Stage I hypertension. The treatment for pre-hypertension is a change of life-style where as recommended treatment of Stage I hypertension is the use of ant-hypertensive drug therapy. The paper, published in the **American Heart Association's** *Hypertension* journal, found there to be a significant variation in central pressure despite individual's having similar cuff pressure. The disparity between these two pressures is largely explained by differences in blood vessel stiffness. The paper concluded that measurement of central pressure will improve the identification and management of patients with elevated cardiovascular risk. This study used the Sphygmocor pulse wave analysis software.

Education – a strong publications base

Atcor is the leading player in the measurement of non-invasive central pressure and arterial stiffness. Its technology is seen as the gold standard which positions the company well to be rewarded from a wider take-up of this technology. There have been over 400 publications covering the Sphygmocor device. The increased use in clinical trials may also see the device used in conjunction with pharmaceutical use in later years.

The clinical trial market is large enough for the company to build a sustainable and profitable business on. To achieve wider adoption is the challenge for the company. The losses recorded in recent years are largely a result of the investment in supporting clinical studies to confirm the benefit of measuring arterial stiffness using the Sphygmocor device and in building creating lobbying and support groups to promote this technology.

Cont'd over

Atcor – from page 4

Financials

In the last financial year the company generated revenue of $6.4 million ($4.8 million in FY2007) and a loss of $3.8 million ($5.2 million loss in FY2007). The company had cash reserves of $3.3 million with a further $1.8 million in directors' loans expected to be recouped by the end of 2009.

We expect the loss in this financial year will be between $2.0 -$2.5 million and for the company to move towards profitability in FY2010. Management anticipates that only a small capital raising (around $1 million), if any, may be required to bring the business to profitability.

Specialists market

To access the specialist market, the company is building awareness in the leading 200 specialists in the cardiology, hypertension and nephrology fields, working through major US centers and throughout the surrounding networks from where the major studies have and continue to be conducted on the use of central pressure measurement.

GP market

The secondary care market presents the largest opportunity for Atcor and will take the longest to cultivate. A key to adoption by general practitioners of the test in the US is allocation of distinct reimbursement code. This is a major task for the company and it has supporting lobby groups to assist with its application. It is expected that the company will file an application for a category I CPT reimbursement code in around 12 months time.

Summary

Atcor is a leading player in the measurement of non-invasive central pressure and arterial stiffness. Its pulse wave analysis technology is seen as the gold standard which positions the company well to be rewarded from a wider take-up of central blood pressure measurement. It is an important test that we believe should be included as a standard measure of cardiovascular disease. There have been over 400 publications covering the Sphygmocor device. The increased use in clinical trials may also see the test used in conjunction with pharmaceutical use in later years.

The clinical trial market for pharmaceutical companies is large enough for the company upon which to build a sustainable and profitable business. To achieve wider adoption is the challenge for the company. The losses recorded in recent years are largely a result of the investment in supporting clinical studies to confirm the benefit of measuring arterial stiffness using the Sphygmocor device and in building and lobbying support groups to promote this technology.

All of the individual major sales divisions are currently profitable for the company. Solid growth in sales is likely for Atcor Medical where it stands to benefit from a major shift over the next five years in the way cardiovascular disease is diagnosed and managed through the use of central blood pressure testing. Atcor is capitalised at $11 million

Bioshares recommendation: **Speculative Buy Class B**

Bioshares

On Track At Halcygen

Halcygen Pharmaceuticals has successfully completed the first of three pharmacokinetic (PK) studies with its lead drug candidate, SUBA-itraconazole. The drug is a reformulation of itraconazole, sold as Sporanox by **Pfizer**, which is the leading itraconazole drug on the market. Itraconazole, an antifungal drug, currently generates annual global sales in excess of US$600 million, including Sporanox and generics.

Itraconazole has an extremely poor absorption profile. Halcygen has accessed the drug reformulation expertise at **Mayne Pharma (Hospira)** which dispersed the drug in a polymer to form microparticles to significantly enhance the dissolution levels of the drug.

This first PK study in the US (five studies have been completed in Australia) compared a 50mg dose of Halcygen's drug with 100mg of Sporanox in a 36 person four-way cross over study. The aim is to generate a comparable absorption profile with SUBA-itraconazole to Sporanox at a much lower dose, which was successfully achieved in this first study at 50% of the Sporanox dose.

Sporanox produces gastrointestinal side effects such as nausea (11%), vomiting (5%) and diarrhea (4%). By reducing the dose and decreasing the amount of drug that remains in the gastrointestinal system, it is expected these side effects will be reduced with SUBA-itraconazole. A comparable half dose form would also have cost of goods savings.

Halcygen is hopeful of registering the drug in the US next year following these three PK studies, seeking a comparable drug with a likely 50% dose. Specific claims of a better safety profile may not be sought however may be assumed at half the dose. Halcygen will meet with the FDA following completion of the PK studies, at which point the FDA will decide whether the company can file under bioequivalence (505(b)(2)) or whether a further study will be necessary to confirm an improved safety profile. Halcygen expects to complete the remaining two PK studies by year's end.

Halcygen is continuing discussions with potential partners to market and distribute the drug. There is currently strong interest to license the drug into parts of Asia and in parts of South America. If further studies are required by the FDA next year, the company may still be in a position to register the drug in other regions based on these PK studies.

The Halcygen program is on track and the company is very well funded, with $11.5 million in cash at mid year and a burn rate of $3.5 million a year.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares

Impedimed Ramps Up Marketing Program

Impedimed (IPD: 72 cents) is commercialising devices used to help clinicians detect early incidence of lymphoedema in women who have had breast cancer surgery. Between 24% - 49% of women experience lymphoedema in the arms post-surgery, according to a recent article published in *The Breast Cancer Bulletin* last month by the National Consortium of Breast Cancer Centers in the US. Diagnosed early and treatment with compression bandages has been shown to prevent long term disability.

The article was written by Dr Steve Schonholz, a prominent breast cancer surgeon who sits on the research committee of the **American Society of Breast Surgeons.** The article has been posted on the Impedimed website. Schonholz is a strong supporter for the prevention of lymphoedema and a user of the Impedimed technology. The technology measures impedance to extracellular electrical flow in limbs to detect increased fluid build up.

Impedimed has coined and trademarked its own L-Dex measurement term (Lymphedema Index) and scale (-10 to +10). In Texas last week, the first 'Know your L-dex' event was held whereby 15% of the 27 women measured were found to have sub-clinical lymphedema, highlighting the immediate usefulness of the Impedimed device. According to the article, measurement for lymphedema using the L-dex index can help detect the condition 10 months before physical symptoms appear.

Impedimed is awaiting FDA approval of its new U400 device for use by doctors (a home care product is already on the market in the US), after which point it will charge around US$25 per reading under its L-Dex agreements with doctors. At least 21 states in the US require insurers to reimburse doctors in treating patients for complications following a mastectomy. There are very active lobby groups for breast cancer around the world, and any treatments that can assist patients are very likely to be favourably received by doctors, regulators, payors and patients. In the US, 2.4 million have had breast cancer and 220,000 are diagnosed with the disease each year.

The company is also planning to file an AMA submission (CPT1 code) for reimbursement for use of its device, which will allow greater coverage outside the use with breast cancer patients. It is anticipated that this specific reimbursement code will be received by the end of 2009. Similar to Atcor Medical, this is a key event for the company.

Impedimed holds an estimated cash balance of $13 million and is capitalized at $63 million.

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Bioshares Model Portfolio (10 October 2008)

Company	Price (current)	Price added to portfolio	Date added
Impedimed	$0.72	$0.70	Aug-08
Antisense Therapeutics	$0.04	$0.07	Aug-08
Mesoblast	$0.83	$1.25	Aug-08
Avexa	$0.13	$0.32	Jun-08
Cellestis	$2.08	$2.27	April 2008
IDT	$1.76	$1.90	March 2008
Circadian Technologies	$0.66	$1.03	February 2008
Patrys	$0.23	$0.50	December 2007
NeuroDiscovery	$0.07	$0.16	December 2007
Bionomics	$0.27	$0.42	December 2007
Cogstate	$0.15	$0.13	November 2007
Sirtex Medical	$1.90	$3.90	October 2007
Clinuvel Pharmaceuticals	$0.21	$0.66	September 2007
Starpharma Holdings	$0.27	$0.37	August 2007
Pharmaxis	$1.90	$3.15	August 2007
Universal Biosensors	$0.69	$1.23	June 2007
Biota Holdings	$0.44	$1.55	March 2007
Probiotec	$1.26	$1.12	February 2007
Peplin Inc	$0.30	$0.83	January 2007
Arana Therapeutics	$0.84	$1.31	October 2006
Chemgenex Pharma.	$0.59	$0.38	June 2006
Cytopia	$0.11	$0.46	June 2005
Optiscan Imaging	$0.15	$0.35	March 2005
Acrux	$0.70	$0.83	November 2004
Alchemia	$0.18	$0.67	May 2004

Portfolio Changes – 10 Oct 2008

IN:
No changes.

OUT:
No changes.

How Bioshares Rates Stocks

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

Group A

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

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

(CMP–Current Market Price)

Group B

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

Speculative Buy – Class A

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

Speculative Buy – Class B

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

Speculative Buy – Class C

These stocks generally have one product in development and lack many external validation features.

Speculative Hold – Class A or B or C

Sell

Corporate Subscribers: Phylogica, Pharmaxis, Biotech Capital, Cytopia,Arana Therapeutics, Starpharma Holdings, Cogstate, Xceed Biotechnology, Optiscan Imaging, Bionomics, ChemGenex Pharmaceuticals, Circadian Technologies, Biota Holdings, Stem Cell Sciences, Halcygen Pharmaceuticals, Peplin, BioMD, Impedimed, QRxPharma, Patrys, Labtech Systems, Hexima, Proteome Systems

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