#### In this edition...

It may have been the most difficult trading conditions since the Great Depression, but Australia's biotech companies have been generating impressive operating results, again highlighting the appeal of investment in this non-cyclical and largely recession-proof industry.

The profit reporting season has delivered some stunning results for Australian biotech companies. CSL and Biota Holdings have produced record results, and Atcor Medical has seen demand for its products surge. Although IDT has had a tough year, with its customers including cash strapped, early-stage biotechs. Please note that next week's edition of Bioshares will be published on Tuesday 1st September.

#### The Editors Companies Covered: ACG, BTA, CSL, IDT

	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)	23.6%
Cumulative Gain	140%
Av Annual Gain (8 yrs)	14.7%

Bioshares is published by Blake Industry & Market Analysis Pty Ltd.

Blake Industry & Market Analysis Pty Ltd ACN 085 334 292 PO Box 193 Richmond Vic 3121 AFS Licence No. 258032

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Individual Subscriptions (48 issues/year) \$320 (Inc.GST) Edition Number 325 (21 August 2009) ISSN 1443-850X

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# Bioshares

21 August 2009 Edition 325

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

### Strong Profit Performance From Biotechs

It may have been the most difficult trading conditions since the Great Depression, but Australia's biotech companies been generating impressive operating results, again highlighting the appeal of investment in this non-cyclical and largely recession-proof industry.

#### CSL - The 'C' Stands for Cash Flow

CSL (CSL: \$32.19) posted a very strong result for the year ending June 30, 2009. The company generated revenues of \$5.04 billion for the year, an increase of 32% in actual terms from the previous year or 16% on a constant currency basis.

Overall sales rose from \$3.6 billion in FY2008 to \$4.6 billion, an increase of 30%. CSL's engine for growth is its plasma products business, CSL Behring, which reported sales of \$3.7 billion, an increase of 38% or 17% in constant currency terms. The largest contributora to growth were immunoglobulin products (up 28%) such as Privigen and Vivaglobin, which represented 33% of CSL Behring sales. Vivaglobin, subcutaneously administered immunoglobulin (16% formulation), is a relatively new product which was launched in March 2006. (CSL recently submitted a biologics license application with the FDA for a 20% liquid formulation version.) CSL management anticipates growth in the order of 12% for FY2010 for CSL Behring.

Sales for the year from the CSL Bioplasma division were \$334 million, an increase of 32% (23% in constant currency terms).

CSL Biotherapies recorded sales of \$502 million, up 5% for the year. This figure included Gardasil sales in Australia of \$159 million, with vaccination of Australian females aged 12-26 now at 75% coverage. It is worth noting that CSL development partner **Merck** is seeking to expand coverage to include females aged 27 – 45 and males aged 9 – 26, in addition to developing a nine-valent vaccine. (Gardasil currently protects against four strains of the human papillomavirus.)

Influenza vaccine sales totalled \$124 million (up 60% for the year). With orders to hand, CSL's influenza production facilities are at full capacity. These orders include 21 million doses of A(H1N1) vaccine for the Australian Department of Health and Aging and a US\$180 million contract with the US Department of Health and Human Services.

## 5<sup>th</sup> Thredbo Biotech Summit

With blizzards forecast this week and over 130 delegates attending, it is sure to be a memorable event!

www.bioshares.com.au/thredbo2009.htm

#### **Net Profit**

CSL's reported profit was \$1.146 billion. However, when the effects of the discontinued acquisition of Talecris are take into consideration, an underlying profit figure of \$1.02 billion was reported, up 45% on the previous year. This is a very strong result for an economic period categorised globally as the most challenging since the Great Depression.

#### Dividend

CSL announced a final unfranked dividend of 40 cents a share, with dividends totalling 70 cents per share for the year.

#### Cash Flow per Share (CPS)

What is especially compelling about the latest result from CSL is the growth in cash flow per share. Cash Flow from Operations stood at \$1.024 billion at June 30, an increase of 49% from the previous year. CPS was \$5.14 per share, an increase of 36% from the previous year, and 97% higher than for the year ending June 30, 2007. This a powerful metric for the CSL business.

#### The Share Buy Back

CSL announced on June 9 it would commence a buy back of up to approximately 9% of its issued capital. The company had raised \$1.9 billion from institutional and retail investors to help fund the acquisition of **Talecris Biotherapeutics Inc**, a bid denied by the US FTC. CSL has opted to return capital by way of the share buy back. As of July 10, the company had acquired 8.5 million shares on market at a cost of \$268 million. To fully return the balance of the \$1.89 billion (which at July 10 stood at \$1.62 billion) CSL could buy at a market price of up to \$34.98 to be cash neutral on the original capital raising.

#### **Outlook Statement for FY2010**

CSL's management expectations for FY2010 are for revenues to be in a range of \$5.2 - \$5.5 billion and for net profit to be in a range of \$1.16 - \$1.26 billion, representing an increase between 14% - 24% on the underlying profit for FY2009. These expectations are based on FY2009 exchange rates. If current exchange rates are sustained (e.g. at AUD/USD =0.84) the FY2010 profit would be expected to be in the range \$1.\$1.1 billion.

What has been contributing to growth in revenues and will continue to support growth, are changes in the mix of immunoglobulin products, such as new formulations of Privigen and Vivaglobin. Approximately one in every five sales dollar comes from sales of immunoglobulin products, which are used to treat patients with immune deficiencies.

#### Summary

CSL is a stand out amongst the Top 50 stocks listed on the ASX, having increased (underlying) profits by 45% and increased cash flow per share by 36% for FY2009. It is the fifteenth largest company by capitalisation listed on the ASX. It is one of less than a handful of manufacturers in that Top 50 group and is it certainly the only sophisticated products manufacturer. The stock is trading on a price/earnings ratio of 16.8. However, adjusted for cash at hand (although we assume this is ultimately intended for the share buy back) (as of July 10) the stock is trading on p/e of 12.4.

We suggest this indicates that CSL is attractive at the current price, with solid growth prospects ahead for FY2010.

Bioshares recommendation: Accumulate

#### Atcor Medical – Sales Surge 47%

Atcor Medical (ACG: 15.5 cents) has reported its full year results for FY2009. The company has increased sales by 74% (47% in constant currency) to \$11.2 million over the year, from \$6.4 million in FY2008, \$4.8 million in FY2007, and \$3.3 million in FY2006. That represents a compounded annual growth rate of 50% a year over the three years.

The company's net loss has reduced to \$1.7 million, from a \$3.8 million loss in FY2008, a \$5.2 million loss in FY2007 and a \$4.0 million loss in FY2006. The transition to a sustainable business should occur in the next six to 12 months for the company as it continues to grow sales whilst investing in market and new product development.

Atcor Medical has developed the gold standard in measuring central blood pressure, called the SphygmoCor system. Central blood pressure is directly correlated to arterial stiffness and therefore cardiovascular disease. Results from studies using the SphygmoCor system have been published in over 400 scientific journals, making this the clear leading device for central blood pressure measurement. In the US, the device has almost no commercial competitors, and in Europe there are some fringe players with other technologies.

However, a technology that is leading the way as a novel preventative health measurement procedure (which is non-invasive) necessitates the market to be established. Although the first mover position can be established, an investment to reach that level is required. Over the next year we anticipate the company's investment into this market and its products will start to deliver a positive return.

The strongest growth in sales over the past year has been from the pharmaceutical sector, where the SphygmoCor system is used in the clinical trials of novel cardiovascular drug candidates. Pharmaceutical sales have doubled and now make up around 60% of the company's sales. The remaining 40% of sales come from sales to universities and teaching hospitals, and also the market which is the most nascent but has by far the largest potential, clinical use by physicians. This clinical practise market showed strong growth in the last year although from a low base.

The data continues to emerge highlighting the use of measuring central blood pressure in conjunction with the standard cuff pressure. Different classes of antihypertensive drugs may have the same effect on cuff pressure but have shown to have quite a different effect on central blood pressure i.e. arterial stiffness and thereby the health of arteries. Some of these drugs have also shown to have a more consistent effect on central pressure than with cuff pressure.

Cont'd over

#### Atcor cont'd

Atcor currently employs 32 people, with four of those based in Europe and the reminder divided evenly between Melbourne and Sydney. Currently 17 people are employed in a sales and marketing role. The company is continuing to work on product enhancements and variations of existing products, having also released a lighter weight second generation SphygmoCor system late last year. It has also invested in real time information data management system for clinical trials, that allows data from trial sites to be instantly transferred to Atcor for processing, called WISDOM.

Atcor Medical is very well placed to benefit from a heightened increase towards preventative healthcare medicine that will increasingly be adopted, certainly in the US and also by other governments around the world over the next decade. Australia has a number of companies that are securing an early position to benefit from this changing healthcare practise. Other local companies include **Impedimed** (prevention of lymphedema following mastectomy), **Universal Biosensors** (point-of-care diagnostics), **Cellestis** (managementof tuberculosis progression from latent to active disease) and even **Pharmaxis** (prevention of lung disease in people with cystic fibrosis) and **Mesoblast/Angioblast** (prevention of heart disease progression) could be put into this category.

Resmed's Peter Farrell has been arguing the case for a decade about the prevention of disease by treating sleep apnea, reducing

the health problems arising from sleep apnea, and the need to move away from a 'sickcare' to a true healthcare system.

Atcor's most recent quarter cash flow was disappointing, with receipts from customers falling to \$2.2 million (net operating cash flow of -\$402,000), after an excellent first quarter result of \$4.5 million receipts (net operating cash flow of +\$924,000). The company had \$3.4 million in cash at the end of June and does not anticipate the need to raise further funds.

We expected solid growth to continue for the next three years. The business is very well managed with strong commercial disciplines in place. The company has secured only around 5% of the clinical trial market for its product and there is significantly more upside in moving this diagnostic measure into daily clinical practise by physicians (both GPs and specialists).

Atcor is capitalised at \$16 million. The company's share price has fallen recently following the latest quarter results. The quarterly variability in operations will likely continue for another six to nine months and provides attractive investment opportunities, with the stock currently trading at only 1.5 times sales.

Bioshares recommendation: Speculative Buy Class A

#### Bioshares Model Portfolio (21 August 2009)

Company	Price	Price added	Date added
	(current)	to portfolio	
ASDM	\$0.39	\$0.30	December 2008
QRxPharma	\$0.55	\$0.25	December 2008
Hexima	\$0.52	\$0.60	October 2008
Atcor Medical	\$0.16	\$0.10	October 2008
CathRx	\$0.27	\$0.70	October 2008
Impedimed	\$0.57	\$0.70	August 2008
Mesoblast	\$1.02	\$1.25	August 2008
Cellestis	\$3.81	\$2.27	April 2008
IDT	\$1.43	\$1.90	March 2008
Circadian Technologies	\$0.72	\$1.03	February 2008
Patrys	\$0.13	\$0.50	December 2007
Bionomics	\$0.24	\$0.42	December 2007
Cogstate	\$0.26	\$0.13	November 2007
Sirtex Medical	\$4.21	\$3.90	October 2007
Clinuvel Pharmaceuticals	\$0.31	\$0.66	September 2007
Starpharma Holdings	\$0.43	\$0.37	August 2007
Pharmaxis	\$2.30	\$3.15	August 2007
Universal Biosensors	\$0.95	\$1.23	June 2007
Biota Holdings	\$1.96	\$1.55	March 2007
Probiotec	\$2.57	\$1.12	February 2007
Peplin Inc	\$0.59	\$0.83	January 2007
Chemgenex Pharma.	\$0.60	\$0.38	June 2006
Cytopia	\$0.10	\$0.46	June 2005
Acrux	\$1.24	\$0.83	November 2004
Alchemia	\$0.50	\$0.67	May 2004

#### Portfolio Changes – 21 August 2009

#### IN:

No changes

#### OUT:

No changes

## \$2.50 \$2.00 \$1.50 \$1.00 \$0.50 Aug-08 Nov-08 Feb-09 May-09 Aug-09

### Stock Updates

#### IDT Australia (IDT: \$1.43) Experiences Difficult Trading Conditions

It's been a tough year for IDT Australia. Weakness in the biotech clinical trial market in Australia and abroad due to the global funding crisis together with Pfizer abandoning a major antibiotic drug candidate that IDT was making has seen revenue fall by 15% to \$26.7 million.

Profitability for the full year has also fallen over the previous year, by 10% to 6.4 million. The company's share price has fallen 18% this week to \$1.42. The company is now capitalized at \$61 million and is trading on a PE ratio of 9.6 times.

The company's dividend will fall slightly, to 5.5 cents per share for this half, with 10.5 cents per share over the full year. This translates to a 7.4% fully franked dividend.

With development funding for new drug programs remaining severely restricted, we expect the following 12 months will remain a difficult period for the company.

IDT Australia is capitalised at \$61 million.

Bioshares recommendation: Hold



#### Biota (BTA: \$1.96) Posts Profit; Hunter Hall Increase Stake

Biota Holdings filed its full year results this week, locking away a net profit of \$38.2 million. Total revenues at \$83.3 millions, which represented an increase of 85% from the previous year's figure. Relenza royalties accounted for \$45 million, \$12.6 million was received as collaboration income and \$20 million came by way of the settlement of litigation with GlaxoSmithKline. Since FY2005, Biota expended \$47.6 million on the GSK litigation. Biota expects to fulfil a \$20 million return of cash to shareholders in December 2009. It is seeking a ruling from the ATO on the degree to which it will be treated as a capital return.

For the year ended June 30, 2009, Biota spent \$13.3 million on research (up 30%) and \$11.3 million on product development (down 26%). Biota's spending on it core business as a drug developer was just under \$30 million for FY2009, although it should be noted that a substantial component of this was funded by collaborators.

We expect Biota to receive significant and substantial royalty income from Relenza sales, with GSK boosting its production capacity to 190 million treatment courses per year.

Hunter Hall lifted its stake in Biota this week increasing its holding from 21.1 million shares (12.1%) to 22.6 million (13.1%) million. Hunter Hall, which also holds a 30% stake in Sirtex Medical, is a positive screen, value growth and ethical investor. It is the largest significant shareholder and only significant institutional holder of Biota stock. From time to time and where it would appear to think its investment continues to fold value, Hunter Hall engages in 'creep' investing, acquiring additional holdings within the 3% creep per six months provision of the Corporations law. It is possible that Hunter Hall will accumulate Biota stock if it perceives that it continues to represent value. As a 'sit and hold' investor, the more Hunter Hall increases its position in Biota stock, the tighter the supply of stock becomes, which may see the stock become less attractive to short term traders.

Biota is capitalised at \$340 million.

Bioshares recommendation: Buy

#### **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

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