#### In this edition ...

We continue our profit reporting coverage of the sector. The global financial crisis has finally taken its toll on many companies in the sector. However during these times the quality companies shine through. Sirtex Medical and Probiotec are two such cases.

And it has been a busy week for Hexima, with approval to start glass house trials of its antifungal corm plants, a deal with Monsanto, and news that its CEO will be moving on.

### The Editors Companies Covered: AMT, AYX, BRC, CMP, CTE, HXL, PBP, SOM, SRX

	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)	66.7%
Cumulative Gain	224%
Av Annual Gain (9 yrs)	20.5%

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# Bioshares

#### 26 February 2010 Edition 349

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

# Sirtex Medical – A Quietly Impressive Result

Sirtex Medical (SRX: \$5.64) has returned a quietly impressive result for the first six months of this financial year. Globally, unit sales increased by 17%, sales increased by 6% and profit before tax (and foreign exchange gains and legal settlement gains) increased by a stellar 49.7%.

The results are particularly good because the period saw a 13.6% increase in the AUD/USD exchange rate over the period (from 74.6 cents to 86.8 cents), and because of the fallout from the global financial crisis. The latter significantly hampered results in the US, particularly in California (not surprisingly), where sales growth was only 9.8%.

In the US, the company has obviously been disappointed, with the President of Sirtex Medical Inc replaced late last year with Michael Mangano, who was previously a senior manager at **Boston Scientific Corporation**.

#### Margins Leap

What was also impressive was the jump in margins for the company. Gross margins increased from 76.1% to 84.2%, and the EBIT margin excluding FX gains/losses and legal gains, increased from 21.0% to 29.0%. Net profit for this half was \$9.1 million.

Unit sales of the Sir-Spheres liver cancer treatment increased from 1706 treatment units to 1996 in this first half. The main growth was in Europe, which increased by a stunning 44%. The US now makes up for about 60% of sales and Europe approximately 40%. The company says that either of these regions or Asia has the potential to become a key driver in the future.

The company increased cash reserves from \$14.8 million to \$34.1 million. No interim dividend will be paid although we suggest a final dividend will.

#### Inflexion Point on Earnings

Sirtex has just hit the inflexion point on earnings. Even though sales increased by only 6%, profit before tax increased by 50% excluding FX gains and losses and any legal settlements. If the company can increase sales by 30% over the next 12 months, then earnings before tax should increase by about 75%.

This continues to make Sirtex a very attractive investment. Operating costs are increasing only at 6% a year, the company is operating on a gross margin of 84% and EBIT margin of 29%. The stock is currently trading on an annualized PE of 23 and a forward PE for the same time next year of only 13.

#### Sales Growth

Sirtex management has traditionally been conservative about its growth forecasts. The company believes that all regions should show strong growth, with double-digit growth for the next five years. The company does not anticipate having any problems with reimbursement continuing for its treatment in the US.

Currently about 250 sites around the world have used the Sir-Spheres treatment. This number will not necessarily increase, with optimization of the appropriate sites more important to the company.

The company will begin selling its product into South Korea and India, although penetration into the Indian market is not expected to be rapid. And more growth in Europe will also come from entry into new markets in that region.

#### Sixteen Clinical Trials in Progress

What will continue to drive sales is increased awareness of the product. At the moment there are around 16 trials underway with the technology. Two of these are major trials, using Sir-Spheres with existing oncology drugs as a first line treatment.

The first of these is the SIRFLOX trial in 400 patients with secondary liver cancer that has spread from the colon. This trial is around one third recruited. Sir-Spheres plus three chemotherapy drugs (FOLFOX) is being compared against FOLFOX.

Another trial recently announced, the SORAMIC study, will be in 375 patients with primary liver cancer. Sir-Spheres plus Nexavar will be compared to the use of Nexavar alone. The trial is being sponsored by Sirtex and Bayer Healthcare and will be conducted in Europe. It's expected to take three years to complete.

At the moment, the product is approved for use in primary and secondary liver cancer treatment in Europe and Australia but only for secondary liver cancer from the colon in the US. A positive result in this trial could see the product used more widely for primary liver cancer, and also as a first line treatment. It is currently used as a third line treatment option. Primary liver incidence is high, particularly in Asia, where hepatitis infection and liver cancer is much more common than in the west.

The important aspect is that this continued investment in clinical trials should result in continued uptake of the treatment. However this expense is in measured proportion. The company currently spends 13.5% of its revenue on R&D and clinical trials. This expenditure has increased by only 14% over the previous corresponding period.

Sirtex has also hired two adopters of the technology as senior medical directors consulting to support the product's use within the medical community. Both are highly experienced with the technology, having conducted over 200 treatments with the Sir-Spheres product and are considered key opinion leaders in this field.

Next on the list for Sirtex is to acquire a product or products that it can sell using the valuable oncology distribution network that it has established. The company is also working on other products, including a radiation protection product for patients undergoing ration therapy.

Ironically, Sir-Spheres are classified as a medical device, however the company more and more is resembling a global pharmaceutical business.

#### Summary

Sirtex remains a very attractive investment opportunity. The company is now moving through an earnings inflexion point where potential strong sales growth (in the order of 30%) should translate into exceptionally strong improvements in earnings. Around 4,000 patients are treated with this therapy each year, making it an established treatment for people with liver cancer. The incidence of liver cancer, the progression of the treatment to a first line therapy, and the wider use for primary liver cancer should ensure demand for the product continues to grow.

Sirtex is capitalised at \$315 million.

Bioshares recommendation: Buy

**Bioshares** 

ltem	Forecast rational	H1 2011 (est.)	H1 2010	Change
		(\$M)	(\$M)	
Sales	30% sales increase	40.6	31.2	30%
Gross Profit	84% (same as 2010)	34.1	26.3	30%
Operating expenses	6% increase (same as 2010)	18.2	17.2	6%
Other revenue	Same as 2010	1.0	1.0	0%
EBIT*		16.8	9.7	74%
NPAT		11.8	See note	
Market Cap.		315		
Fwd PE (February 2011)*		13.4	23.2**	

## Sirtex Medical Financials

\* Excludes FX and legal settlement awards

Note: Actual net profit w as \$9.1 million. How ever this included FX losses and legal payouts. Excluding these items and taxed at 30%, the company w ould have generated a net profit of \$6.8 million in H1 2010.

\*\* Based on \$6.8 million half year net profit

# Changes at Hexima

Hexima's (HXL: 47 cents) CEO, Josh Hofheimer, has announced that he will step down in July after two years at the helm. Hofheimer was a high level appointment for Hexima, coming to the company with the experience of structuring agbio deals as a lawyer from both the licencee and licensor sides.

Hofheimer will relocate to the US with his family. His original contract was for two years. We speculate that the company and Hofheimer could not agree on new contract terms, as well as Hofheimer wanting to return to the US. Hofheimer was paid \$585,000 in FY2009 and does not come cheaply to the company, however his departure is disappointing for the company with his skills base difficult to replace.

We are comfortable that the decision to step down is not related to the underlying technology. Hofheimer will remain a consultant to the company and will stay on the board for a certain period. The company is currently seeking a new CEO.

#### **Deal with Monsanto**

This week Hexima announced a cross-licensing deal with **Monsanto**. Monsanto will gain a research license and commercial license to one of Hexima's three technologies, called the MGEV technology. It is the second such deal with **DuPont** signing up for access to the same multiple gene insertion technology last year.

In the cross license, Hexima will gain access to some of Monsanto's bt insect control genes. Hexima has its own insect resistant technology and this agreement will allow it to stack its own genes with the proprietary Monsanto genes. It has been a busy week for the company. In another development Hexima announced that it had received PC2 certification for its glass house facility, allowing the company to now start growing genetically modified cops at that facility. The company should have its first leads by the end of March which it can start growing in the glass house. The growth cycle for corn is 105 days so the first plants should starting coming through around mid year.

The company can grow up to 10,000 different combinations of its biotech corn using antifungal protein combinations, which will be tested at the facility against the six main fungi that are commercial issues with corn crop production.

Milestones for the company to look out for include progress with glasshouse corn production, further MGEV agreements, and a decision by DuPont to progress with the antifungal technology for application in soy crop production.

Hexima is capitalized at \$37 million. At the end of last year the company had \$25.5 million in cash, which should be sufficient for three years of operation. Within three years, the company could be in the position that glasshouse trials would be completed, leads optimised, and DuPont deciding to progress the program to filed trials. This would be a major transformation point for the company.

Bioshares recommendation: Speculative Buy Class A

**Bioshares** 

#### Correction

On page 1 of Bioshares 348 we incorrectly stated that Biota's costs of it recent acquisitions would amortised over 10 years when in fact the amortisation woulc occur over 10 months. The corrected sentence should read "Acquisition costs, of around \$13 million for the two companies, will be amortised over 10 years and falls into the R&D cost base."

# More Half Yearly Results: Profit Reporting Companies

ASDM (AMT)	
CMP	\$0.52
Capitalisation (\$M)	\$18
PE (Annualised)	180

Period	H1 2008	H2 2008	H1 2009	H2 2009	H1 2010
Sales (\$M)	\$2.7	\$4.1	\$2.8	\$3.4	\$2.7
% ch, prev. period		53%	-32%	19%	-20%
EBITDA (\$M)	-\$1.4	\$2.3	-\$1.0	\$0.2	\$0.60
% ch, prev. period		N.A	N.A	N.A	N.A
Depreciation		-\$0.6	-\$0.4	-\$0.4	-\$0.6
EBIT (\$M)	-\$1.4	\$1.7	-\$1.4	-\$0.2	\$0.0
% ch, prev. period		N.A	N.A	N.A	N.A
Interest (\$M)		-\$0.1	-\$0.05	-\$0.9	-\$0.05
Tax (\$M)	\$0.5	-\$0.5	\$0.5	\$0.2	\$0.06
NPAT (\$M)	-\$1.0	\$1.1	-\$1.0	-\$0.1	\$0.05
% ch, prev. period		N.A	N.A	N.A	N.A

Austofix (AYX)	
CMP	\$1.00
Capitalisation (\$M)	\$11
PE (Annualised)	17

Period	H1 2008	H2 2008	H1 2009	H2 2009	H1 2010
Revenue (\$M)	\$0.6	\$0.8	\$0.9	\$0.6	\$1.8
% ch, prev. period		29%	17%	-30%	181%
EBITDA (\$M)	-\$1.0	-\$1.0	-\$0.5	-\$0.8	\$0.0
% ch, prev. period		6%	-52%	N.A	N.A
Depreciation	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
EBIT (\$M)	-\$1.0	-\$1.0	-\$0.5	-\$0.8	\$0.0
% ch, prev. period		6%	-52%	N.A	N.A
Interest (\$M)	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Tax (\$M)	\$0.0	\$0.1	\$0.4	\$0.2	\$0.3
NPAT (\$M)	-\$1.0	-\$0.9	-\$0.1	-\$0.6	\$0.3
% ch, prev. period		-6%	-89%	N.A	N.A

Brain Resource Company (BRC)	
CMP	\$0.27
Capitalisation (\$M)	\$25
PE (Annualised)	16

Period	H1 2008	H2 2008	H1 2009	H2 2009	H1 2010
Revenue (\$M)	\$3.1	\$1.3	\$3.1	\$4.3	\$4.0
% ch, prev. period		-57%	130%	37%	-5%
EBITDA (\$M)	\$3.0	-\$5.8	\$3.4	\$0.0	\$0.7
% ch, prev. period		-291%	N.A	-99%	1947%
Depreciation	-\$0.1	\$0.0	-\$0.1	-\$0.1	-\$0.1
EBIT (\$M)	\$3.0	-\$5.8	\$3.3	\$0.0	\$0.7
% ch, prev. period		-297%	N.A	-101%	N.A
Interest (\$M)	\$0.5	\$0.7	\$0.5	\$0.4	\$0.1
Tax (\$M)	\$0.1	\$0.2	\$0.1	\$0.0	\$0.0
NPAT (\$M)	\$3.5	-\$5.0	\$3.8	\$0.4	\$0.8
% ch, prev. period		-243%	N.A	-91%	125%

#### **Advanced Surgical Design & Manufacture**

ASDM manufactures surgical and medial equipment at its facility in Sydney. ASDM posted a profit of \$51,000 for the latest half year.

Although ASDM recorded a strong headline revenue result for the H1 2010 of \$3.97 million, underlying sales were much softer at \$2.7 million (-20% from the previous period). The difference was made up with a one-off sale of IP covering the Active Uni-Compartmental Knee to Stryker for \$1.28 million.

The company has applied the funds it has gained towards the development of the PAD, a device that is being investigated in the re-vascularisation of limbs. ASDM holds manufacturing rights to the PAD from AllVascular Pty Ltd.

Bioshares recommendation: Hold

#### Austofix

Adealide-based Austofix designs, develops and distributes orthopaedic implants.

The company has posted a maiden half year profit of \$0.3 million. However, on an EBIT basis the result was netted out.

The company is growing sales, recording \$1.78 million for the latest half year period, which represented an increase of 181% from the previous period.

The company expects to grow export revenues in the medium term, with the company focusing on finalising distribution agreements in Europe and elsewhere.

Bioshares recommendation: Under Review

#### **Brain Resource Company**

The Brain Resource Company exploits a unique database of 165 standradised variables of brain performance, with application in the clinical trial arena, in personalised medicine and in well-being assessment.

BRC lodged a half yearly profit result of \$0.8 million, an increase of 125% from the previous period. However, sales dipped by 5% from the previous period to close at \$4 million for the half year.

Bioshares recommendation: Not Formally Covered

Compumedics (CMP)	
CMP	\$0.18
Capitalisation (\$M)	\$29
PE (Annualised)	44

Period	H1 2008	H2 2008	H1 2009	H2 2009	H1 2010
Revenue (\$M)	\$17.1	\$21.5	\$16.8	\$21.6	\$15.3
% ch, prev. period		26%	-22%	28%	-29%
EBITDA (\$M)	\$2.5	-\$1.2	\$2.5	\$0.7	\$0.3
% ch, prev. period		-150%	N.A	-73%	-51%
Depreciation	\$0.0	-\$0.6	\$0.0	-\$0.4	\$0.0
EBIT (\$M)	\$2.5	-\$1.8	\$2.5	\$0.3	\$0.3
% ch, prev. period		-172%	N.A	-89%	23%
Interest (\$M)	-\$0.3	-\$0.4	-\$0.3	-\$0.2	-\$0.2
Tax (\$M)	\$0.0	\$0.1	\$0.0	\$0.0	\$0.0
NPAT (\$M)	\$2.5	-\$1.7	\$2.5	\$0.3	\$0.3
% ch, prev. period		-169%	N.A	-89%	23%

Cyrosite (CTE)	
CMP	\$0.15
Capitalisation (\$M)	\$7
PE (Annualised)	164

Period	H1 2008	H2 2008	H1 2009	H2 2009	H1 2010
Sales (\$M)	\$3.7	\$2.8	\$3.2	\$3.0	\$3.1
% ch, prev. period		-25%	16%	-8%	3%
EBITDA (\$M)	\$0.5	\$0.0	\$0.29	-\$0.3	\$0.03
% ch, prev. period		-101%	-10511%	-215%	N.A
Depreciation	-\$0.2	\$0.0	-\$0.2	\$0.0	-\$0.1
EBIT (\$M)	\$0.3	\$0.0	\$0.1	-\$0.4	-\$0.1
% ch, prev. period		-103%	-1465%	-371%	-83%
Interest (\$M)	\$0.1	\$0.0	\$0.09	\$0.1	\$0.08
Tax (\$M)	\$0.0	\$0.0	\$0.0	\$0.2	\$0.0
NPAT (\$M)	\$0.4	\$0.0	\$0.225	-\$0.2	\$0.021
% ch, prev. period		-96%	1140%	-168%	N.A

#### Probiotec (CMP)

CMP	\$1.52
Capitalisation (\$M)	\$83
PE (Annualised)	7

Period	H1 2008	H2 2008	H1 2009	H2 2009	H1 2010
Revenue (\$M)	\$32.8	\$33.3	\$46.5	\$40.7	\$39.8
% ch, prev. period		1%	40%	-12%	-2%
EBITDA (\$M)	\$5.5	\$7.1	\$8.2	\$8.7	\$9.6
% ch, prev. period		28%	16%	6%	10%
Depreciation	-\$1.1	-\$0.9	-\$1.1	-\$2.7	-\$1.6
EBIT (\$M)	\$4.4	\$6.2	\$7.1	\$6.0	\$8.0
% ch, prev. period		39%	16%	-15%	33%
Interest (\$M)	-\$0.9	\$0.0	-\$1.1	-\$0.9	-\$0.7
Tax (\$M)	-\$1.0	-\$1.2	-\$1.7	-\$1.4	-\$1.1
NPAT (\$M)	\$2.5	\$3.8	\$4.3	\$4.6	\$6.2
% ch, prev. period		56%	11%	9%	35%

#### Compumedics

Compumedics designs, manufactures and markets sleep diagnostic systems. Historically, both revenues and profits for Compumedics are quite variable. Sales decreased by 29% to reach \$15.3 million for the lastest half year.

NPAT for the period was \$0.33 million, up 23% from \$0.27 million for the previous period.

Compumedics cited the late receipt of FDA approval for a new product as a factor in the fall off in sales, as well as generally weakened conditions in the USA. The compmany expects to fulfill outstanding orders now that the Grael HD-PSG high definition sleep diagnostic system has been approved.

Bioshares recommendation: Under Review

#### Cryosite

Cryosite is a specialist biologicals storage and service company. It also operates a cord blood service.

The company increased sales by a modest 3% for latest half year period, compared to the previous periods, and posted a very small profit of \$21, 358 for the H1 2010.

Cryosite's generally flat sales can be attributed in part to its exposure to the clinical trials sector, which is likely to have become subdued in the last several years as many drug development activities have been cut back at the local level.

Bioshares recommendation: Not Formally Covered

#### Probiotec

Probiotec markets and manufactures prescription and OTC products, nutritional products and also provides contract manufacturing services. The company has been shifting its focus towards branded products.

The company recorded sales of \$39.8 million for the latest half year period, which represented a modest 2% fall from the previous half year period. However, NPAT increased by 35% to \$6.2 million for H1 2010.

What stands out in the PBP figures is the consistent growth in EBITDA, which increased 10% in the latest period, following increases of 6%, 16% and 28%. This can be seen in margins increasing from 43% in FY2008 to 53% for the latest period.

For the full year to June 2010, the company has provided guidance that it expects NPAT to grow by 20%.

Bioshares recommendation: Buy

Somnomed (SOM)	
CMP	\$0.95
Capitalisation (\$M)	\$36
PE (Annualised)	30

Period	H1 2008	H2 2008	H1 2009	H2 2009	H1 2010
Revenue (\$M)	\$1.5	\$2.2	\$3.2	\$4.6	\$5.0
% ch, prev. period		44%	47%	43%	9%
EBITDA (\$M)	-\$1.3	-\$1.3	-\$1.3	-\$0.4	\$0.2
% ch, prev. period		0%	-1%	-69%	N.A
Depreciation	-\$0.2	-\$0.2	-\$0.1	-\$0.2	-\$0.1
EBIT (\$M)	-\$1.5	-\$1.5	-\$1.4	-\$0.6	\$0.1
% ch, prev. period		-2%	-6%	-57%	N.A
Interest (\$M)	\$0.0	\$0.2	\$0.2	\$0.1	\$0.0
Tax (\$M)	\$0.0	\$0.0	\$0.0	\$0.0	\$0.4
NPAT (\$M)	-\$1.5	-\$1.2	-\$1.2	-\$0.6	\$0.6
% ch, prev. period		-18%	0%	-53%	N.A

#### Somnomed

Somnomed markets the Somnodent randge of dental products for use in treating obstructive sleep apnea.

For the last half year period, the company broke into profitability with a profit of \$0.6 million. Somnomed generated sales of \$5 million for the latest half year period, an increase of 9% from the previous period.

The company sold 9,140 units in the latest period, an increase of 35% from 6,679 units sold in the previous half year period.

Somnomed may be a company to track more closely if it can sustain growth in unit sales, which have tripled from the half year ending December 31, 2008.

Bioshares recommendation: Under Review

#### Notice

*The Burrill Report* brings monthly analysis on biotech's performance on the global capital markets including how much capital is being raised, what partnering/M&A deals have been done and why, FDA product approvals and failures, critical PDUFA dates, news on clinical trials, patents awarded, drug approvals and executive changes. The publication draws on the expertise of Burrill & Company's team of biotechnology professionals. For a sample issue contact Peter Winter, Editor pwinter@b-c.com

Company	Price	Price added	Date added
	(current)	to portfolio	
Tissue Therapies	\$0.23	\$0.21	January 2010
Biodiem	\$0.22	\$0.15	October 2009
QRxPharma	\$0.90	\$0.25	December 2008
Hexima	\$0.47	\$0.60	October 2008
Atcor Medical	\$0.16	\$0.10	October 2008
CathRx	\$0.28	\$0.70	October 2008
Impedimed	\$0.73	\$0.70	August 2008
Mesoblast	\$1.85	\$1.25	August 2008
Circadian Technologies	\$0.54	\$1.03	February 2008
Patrys	\$0.14	\$0.50	December 2007
Bionomics	\$0.29	\$0.42	December 2007
Cogstate	\$0.30	\$0.13	November 2007
Sirtex Medical	\$5.64	\$3.90	October 2007
Clinuvel Pharmaceuticals	\$0.26	\$0.66	September 2007
Starpharma Holdings	\$0.73	\$0.37	August 2007
Pharmaxis	\$2.57	\$3.15	August 2007
Universal Biosensors	\$1.85	\$1.23	June 2007
Probiotec	\$1.52	\$1.12	February 2007
Acrux	\$2.05	\$0.83	November 2004
Alchemia	\$0.68	\$0.67	May 2004

#### Portfolio Changes – 26 February 2010

IN:

No changes.

**OUT:** No changes.

tially speculative propositions, <i>Bioshares</i> grades them according to relative risk within that group, to better reflect the very large spread of risk within those stocks.		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.		
Group A Stocks with exist flows.	sting positive cash flows or close to producing positive cash	<i>Speculative Buy – Class B</i> 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		
Buy Accumulate	CMP is 20% < Fair Value CMP is 10% < Fair Value	management or board may need strengthening. Speculative Buy – Class C		
Hold	Value = CMP	These stocks generally have one product in development and lack		
Lighten	CMP is 10% > Fair Value	many external validation features.		
Sell (CMP–Current	CMP is 20% > Fair Value t Market Price)	Speculative Hold – Class A or B or C Sell		
	,	Holdings, Cogstate, Bionomics, ChemGenex Pharmaceuticals,		
		als, Peplin, Impedimed, QRxPharma, Patrys, Labtech Systems,		
Hexima, Tyri	an Diagnostics, Mesoblast, Atcor Medical, CathRx,	BioMd, Tissue Therapies		
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		ates (inc. GST) tronic distribution): \$350		
		vithin \$550 2-3 email addresses		
	the same business cost centre, ou	r \$750 4-5 email addresses		
	pricing structure is as follows:	\$950 6-10 email addresses		
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# **Bioshares**

#### **How Bioshares Rates Stocks**

Ph ( )

Emails

For the purpose of valuation, Bioshares divides biotech stocks into

without near term positive cash flows, history of losses, or at early

stages of commercialisation. In this second group, which are essen-

two categories. The first group are stocks with existing positive cash flows or close to producing positive cash flows. The second group are stocks

#### Group B

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

These stocks will have more than one technology, product or

Speculative Buy - Class A