

In this edition...

In what appears to be a key scientific advance, Stem Cell Sciences researchers have worked out how to grow rats from rat embryonic stem cells. This is a breakthrough for the drug discovery industry.

Ventracor generated significant sales (\$17 million) of its heart assist device in FY2008 and appears to be a clear number two in the race to market with its second generation LVAD.

We also review thirteen profitable life science companies.

Companies covered: AMT, CLV, COH, CMP, CSL, CST, CTE, ELX, IDT, ITD, PBP, RMD, STC, SRX, TIS, VCR

Bioshares

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

Stem Cell Smarts About To Pay Off

Stem Cell Sciences (STC: 25 cents) has long been respected for its leading expertise and intellectual property position in the stem cell field. Just how the company was going to prosper from that knowledge and from those technology assets in the short to medium term has remained uncertain. However, scientists linked to the company, including Austin Smith, have just announced the development of the technology needed to make transgenic rats from rat-derived embryonic stem cells.

A Scientific Breakthrough, A Drug Research Breakthrough

This is the first time it has been shown that genetically altered rats will be able to be produced from rat embryonic stem cells. What this allows is the ability to grow rats that have specific genes added or deleted to help in the screening of new pharmaceuticals. Rats have far more genes in common with humans than do mice. Hence the technology represents a breakthrough for drug researchers.

The technology has been used to develop the knock-in (genes added) or knock-out (genes deleted) mice over the last 20 years but to date has been unable to be achieved in rats. There are advantages of using the rat as an animal model in that they are judged as being more predictable of some human diseases, including psychiatric, neurological and cardiovascular diseases.

The market for transgenic mice is estimated at several hundred millions of dollars a year and has helped build highly successful international biotech businesses such as **Deltagen**, **Regeneron** and **Lexicon Pharmaceuticals**. Stem Cell Sciences estimates that the annual global market for transgenic rats for pharmaceutical research could be valued in excess of US\$80 million a year. Stem Cell Sciences plans to license the technology to service providers to the pharmaceutical industry, with potentially a multimillion dollar upfront payment and royalties from sales on offer. The company may control the production of the rat embryonic stem cells in-house. Stem Cell Sciences is aiming to secure licensing arrangements as soon as possible.

What makes the results more compelling is that experiments have been replicated several times in two independent laboratories, validating the discovery. The first transgenic rat using this technology should be produced within 12 months and the technology could be available to pharmaceutical companies within two to three years. It is clearly the largest scientific development for Stem Cell Sciences this year. The breakthrough is expected to be published in a major scientific journal in the next three months. Stem Cell Sciences has filed patents over the rat embryonic stem cells and the culture medium used to grow the cells. With a capitalisation of only \$8 million, and with \$3.7 million in cash at mid-year, Stem Cell Sciences has become a very appealing investment with greater clarity over where medium term revenue growth will be achieved.

Bioshares recommendation: Speculative Buy Class B

	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)	-8.0%
Cumulative Gain	90%
Av Annual Gain (7 yrs)	17.8%

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Ventracor – LVAD Market Starts Break-out

Within two years time, Ventracor (VCR: SP 20 cents: Cap. \$62 million) should have its LVAD heart pump approved and on sale in the US market for bridge-to-transplant (BTT) patients. Its device is already approved for use in Europe, parts of Asia and Australia, and the company is generating sales of the device in the US through clinical trials. However, the key region is the US, and with that market rapidly expanding thanks to the approval of competitor **Thoratec**'s second generation device, Ventracor is well placed to enter what should be a sizeable US market as the number two player.

LVAD market accelerating

In April this year, the leading player in the LVAD (left ventricular assist device) space, **Thoratec**, had its second generation LVAD approved by the FDA, the Heartmate II for BTT. As expected, this has had a major positive impact on the LVAD market.

As of April 25 this year, Thoratec had over 1300 patients implanted with its Heartmate II according to its quarterly report. Following approval on April 21 of the Heartmate II in the US, this figure jumped to over 1600 implant devices by the end of June worldwide.

The US accounts for approximately 75% of the global LVAD market, largely due to the reimbursement of the device and procedure, which will be US\$131,000 in 2009. An analyst report from Canaccord Adams estimates that around 750 Heartmate II systems are expected to be sold this year in the US alone, and close to 1300 LVAD systems worldwide by Thoratec generating revenue of just under US\$200 million. This revenue figure is expected to increase to around US\$300 million by 2010.

Thoratec previously had a bulky and awkward first generation system approved (Heartmate XVE) which is still selling. This system weighs just under 1.2 kg, has two valves and many moving parts. By comparison the Ventracor LVAD, the VentrAssist, is about one quarter of the weight with no valves and only one moving part. The approval in the US of a significantly more reliable and smaller LVAD, the Thoratec Heartmate II, is quickly opening up the massive potential LVAD market. This is great news for Ventracor, which is two years behind Thoratec with, according to clinical trial results, an even more reliable LVAD.

But there may be even more good news for LVAD players. It's expected that by early to mid 2010, Thoratec will also have its device approved for destination therapy (DT), whereby the device is implanted into patients who have terminal heart disease and are even too sick to be accepted for a heart transplant. This has the potential to create an annual billion dollar market.

The release of a reliable LVAD system into the US market is also beginning to cause a blurring between the BTT and DT classifications. This is an important and understandable trend. Cardiologists can recommend patients for an LVAD if they 'intend' to place them on the transplant list, giving them access now to the newly approved Heartmate II device which is not currently approved for

the more ill DT patients. Only about half of the patients on the BTT program are on the transplant list.

There are around 2000 heart transplants conducted each year in the US, and we estimate the BTT market in the US at 4000 devices a year, or around US\$400 million. There is no immediate limit from the number of eligible patients in the US who could benefit from an implanted LVAD, with acceptable estimates of numbers in excess of 100,000 a year. However, realistically, restraints from health budgets and capacities at transplant and cardiac surgery centres will govern a more measured uptake to a market that could reach between US\$800 million - US\$1 billion within five years worldwide.

Device sales

In the financial year just ended, Ventracor's sales surged, from \$4.9 million in 2007 to \$17.3 million in 2008. The company sold 189 devices and generated a net loss \$25 million. Payment for devices is generally quick, within 30-40 days of sale.

Sales increased to \$2.1 million in Australia and Asia, with predominantly wealthy patients in Hong Kong and India contributing to those sales. In Europe, sales increased significantly by \$4.2 million to \$5.9 million. And in the US, sales increased by \$7.3 million to \$9.3 million.

In Europe, Germany was a significant contributor (around 50% of sales), where the device is sold and the controller is rented, providing an annuity stream to the company. The device sells for a higher price in Europe, at 75,000 Euros. A key factor to increasing the market in Europe is gaining reimbursement in France, which may occur by the end of 2008.

In the US, sales has come through reimbursement from Medicare for devices used in clinical trials. Most people over the age of 65 are covered under the Medicare system and all patients being recruited into the trials must have coverage from payors. Given that the most people for which an LVAD system is suitable for are over the age of 65, explains the appeal of the US for the LVAD market.

It is also important to note that once Ventracor's clinical trials in the US are finished, it can continue to enroll patients (and sell devices) under the Continued Access Protocol. Thoratec has been enrolling around 200 patients a year under this CAP in its DT trial of its Heartmate II device. The CAP system should allow Ventracor to maintain US sales whilst its device is awaiting FDA approval.

Clinical trials update

To date more than 325 patients have been implanted with the Ventracor device with the longest surviving patient implanted for just under four years. In the CE Mark Bridge Trial, 33 patients were implanted with an 82% success rate in reaching the goal of survival or transplant at 154 days. In the US BTT trial, 82% of the 28 patients in the feasibility trial survived to the same endpoint at 180 days. This was a better result than the Thoratec Heartmate II US

Cont'd over

Ventricor cont'd

BTT trial, which achieved a 74% success rate for the same endpoint. That device was approved, even though it did not meet the set goal of 75% success at 180 days.

Ventricor has completed 97 implants (with 52 patient outcomes received so far) in the US BTT trial, with 98 patient outcomes required at which point it will conduct an interim analysis. From that point, either the trial will continue to the planned 140 implants (patient outcomes). However if the data shows the device has sufficiently met endpoints, then the company may be in a position to file the device for BTT approval in the US on the interim data.

The DT trial has fallen behind schedule, with only 46 patients included to date, including the control arm (up from 15 in February), with 225 to be enrolled in total. The reason for slower recruitment rate is that the surgeons have wanted to gain more experience with the BTT implants, before implanting the sicker DT patients. There are two modules in this arm. Module A is recruiting healthier patients and comparing against standard drug therapy. The patients in a more dire health position, some with only weeks to live, are allocated to Module B, where the company's VentrAssist device is being compared against the only LVAD approved for destination therapy in the US, the first generation Heartmate XVE.

Comparison with heart transplant

The reliability of LVAD systems and the patient survival records have improved substantially with the introduction of second and third generation systems. Direct comparison data with heart transplant is difficult to obtain with the newer systems because most the data available measures only in the BTT group, up to when the patients either receive a transplant or for 180 days post implant.

Data from the DT trials will also not be a direct comparator, because these are patients who are very ill and ineligible for a heart transplant. Taking that into account, historical data shows that one-year survival rates in heart transplant recipients is around 86%. The Ventracor data of 86% survival at six months indicates that Ventracor's LVAD is gaining ground on heart transplants as measured by short term survival. At three years the survival for a heart transplant is around 77% and there is no data available to compare the Ventracor device, although there are some patients approaching four years with living with the device.

These measures do not include patient comfort. Heart transplant recipients can lead more normal lives although are required to have chronic anti-rejection drug therapy. LVAD systems remain awkward with a percutaneous lead through the skin and a controller having to be worn on a harness set up.

Ventricor is working on a fully implantable system, which if successful, has the potential to become a market leading product and increase the appeal and usability of LVAD system. It remains to be seen whether the regulatory approval process can be streamlined with this future advance over the next three years, given the pump itself will remain unchanged.

Capital raising

Ventricor had \$18 million at mid year and is currently seeking to raise additional capital of around \$20 million for the next 12 months of operation. There are expectations that the business should become cash flow positive over the next two to three years. This is a reasonable expectation, with the company's VentrAssist device we anticipate to be approved for use in the US by mid 2010 and given the rapid adoption of the competing second generation Heartmate II device since approval for BTT in April this year.

Risks

The risk with all mechanical heart pumps is the expected future success of stem cell therapy. However there will likely be degrees of efficacy of stem cell therapies which remain a number of years away and it's unlikely they will provide a cure-all solution to cardiovascular disease. Stem cell therapy potentially could also be used in conjunction with LVAD therapy to help unload the heart during cell therapy to better facilitate the heart re-growth.

Summary

The global market potential for LVADs is arguably somewhere between US\$1 billion - US\$4 billion a year. Currently the market for LVADs is around US\$300 million a year. Although there are up to 10 groups with LVAD programs, the two clear leaders are Thoratec and Ventracor. Competitors that are less advanced will find it more difficult to break the market dominance that the first two or three leaders establish unless substantial improvements in performance or usability are offered.

Ventricor is well positioned to leverage from the rapid expansion of the LVAD market by Thoratec from the introduction of a more reliable heart pump. With Ventracor's product expected to reach the US market within two years, profitability for the business may coincide in a similar timeframe.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares

FY2007-08 Profit Reviews

The Australian listed life science sector includes a number of companies that are not only securing profits but are growing profits, in some cases after many years spent developing products and developing markets.

The activities of these companies range from plasma fractionation (CSL), API manufacturing (IDT Australia), OTC and prescription pharmaceutical manufacture (Probiotec), tuberculosis diagnostics (Cellestis) and liver cancer therapy (Sirtex Medical).

Brief financial summaries and comments follow for 13 companies reporting profits for the year ending June 30, 2008.

ASDM – 23% lift in sales

Australian Surgical Design and Manufacture is a relatively recent listing on the ASX. The Sydney-based company designs and manufactures prosthetic implants and surgical tools. ASDM posted a modest profit for FY2008 (\$0.2 million), although the highlight was a 23% increase in sales that followed a 26% increase in the previous year.

The company is active in new product development. ASDM has manufacturing rights to the Peripheral Access Device, a device that re-pressurises blood flow, and has the potential to prevent limb amputation and also be used in cardiac bypass surgery. The PAD has been evaluated in ten patients to date.

ASDM			CMP	\$0.45
AMT	Cap'n (\$M)	\$16	PE	88
	FY2005	FY2006	FY2007	FY2008
Sales (\$M)	\$4.5	\$4.4	\$5.6	\$6.8
Change		-1%	26%	23%
EBIT (\$M)	\$0.64	-\$0.14	-\$0.12	\$0.29
Change		-123%	-18%	NA
Net Profit (\$M)	\$0.27	-\$0.32	-\$0.45	\$0.18
Change		-217%	42%	NA

Cellestis – Posts maiden profit

Cellestis recorded a maiden profit of \$2.26 million after posting sales of \$18.8 million. The Cellestis technology was initially developed at the CSIRO and then incubated at CSL. The TB diagnostic technology was shifted into the Cellestis vehicle by founders Tony Radford and Jim Rothe in November 2000.

FY2008 was an historic year for Cellestis as it posted its first ever profit. While sales have been a long time coming, the year on year growth has been impressive. Sales rose 77% in FY2008 from the previous year. Since FY2005, sales have increased 900%. The company's high PE ratio will be tested if sales in FY2009 and FY2010 are not sustained at very high rates of growth.

Cellestis			CMP	\$2.19
CST	Cap'n (\$M)	\$210	PE	93
	FY2005	FY2006	FY2007	FY2008
Sales (\$M)	\$1.9	\$5.3	\$10.7	\$18.8
Change		178%	102%	77%
EBIT (\$M)	-\$3.63	-\$3.62	-\$2.28	\$2.26
Change		NA	NA	NA
Net Profit (\$M)	-\$3.35	-\$3.62	-\$2.28	\$2.26
Change		NA	NA	NA

Clover Corp – Turns the corner

Clover Corporation is a developer and manufacturer of functional foods, including a specially formulated and encapsulated fish oil product that is used in infant formula.

Clover reported sales of \$21.6 million, representing an increase of 31% from the previous year. Clover's latest profit result of \$4.14 million (up 515%) is welcome indeed, coming on the back of a lack lustre string of profit results. However, adjusted for a \$1.3 million tax benefit, net profit was \$2.8 million for the year.

Clover Corp			CMP	\$0.22
CLV	Cap'n (\$M)	\$36	PE	13
	FY2005	FY2006	FY2007	FY2008
Sales (\$M)	\$14.3	\$17.3	\$16.5	\$21.6
Change		21%	-5%	31%
EBIT (\$M)	\$1.07	\$1.03	\$1.30	\$3.04
Change		-4%	26%	135%
Net Profit (\$M)*	\$0.77	\$0.45	\$0.64	\$2.80
Change		-41%	40%	341%

* adjusted for FY08

Clover's growth in sales was driven by sales of infant formula additives in the Asia Pacific region. In a related development the company has signed a five year contract (and now commenced supplying) with Mead Johnson to supply 50% of its needs for HiDHA tuna oil and HiDHA Driphorm powder in product applications for children greater than 12 months of age.

Cochlear – Strong AUD weakens earnings by \$21 M

Global hearing implant manufacturer Cochlear grew sales by 8% for FY2008 and net profit by 15% for the same period. The company ascribed a negative \$21 million impact of a strong AUD over the fiscal year on the company's core earnings. (Adjusting for currency impacts, sales increased by 18%.) Sales of cochlear implants grew 5%, to \$504.5 million, whereas the sales of the bone anchored system (Baha) performed strongly, rising 21% to \$75.9 million. By region, the strongest growth occurred in Europe, up 30% in constant currency terms, followed by Asia/Pacific (up 20%) and the Americas (up 6%). Cochlear's gearing ratio fell slightly over the fiscal year, down from 31% to 29%.

Established markets' growth for cochlear implants is expected to benefit from customers who opt for a second implant, with 15%-20% of implants in those markets being for a second implant.

Compumedics – Sustainable profits an elusive goal

Compumedics manufactures and sells sleep and neurological diagnostic equipment. Sales improved marginally for FY2008, increasing 5% to \$38 million. Overall sales have effectively been flat for the last four years. The company turned a small profit of \$0.8 million for the year just ended.

Administration costs in the Compumedics business totalled \$4.8 million for FY2008. These costs have been constant at about 13% of sales for the last four years.

The company's R&D spend for FY2008 was \$4.6 million, or 12% of sales. R&D spend has fallen markedly; in FY2005 it was \$8.9 million or 23% of sales. Significant and sustainable growth in profitability has proved an elusive ambition for Compumedics.

Cryosite – Relocating to cater for growth

Cryosite is a company that specialises in the storage of biological products, including clinical trial tissue samples and cord blood collections.

Cryosite is a minnow of a company, capitalised at \$6 million. This company generated sales in excess of its capitalisation for FY2008, of \$6.6 million. Net profit fell 55% over the year to \$0.45 million. To cater for increases to future expected demand for its services, the company is relocating from its premises in Lane Cove to larger premises in South Granville. The company spent \$0.35 million on relocation expenses in the FY2008 period.

The company expects strong growth in clinical trials to support growth in the company's business. The company has 50 clients in the area and is associated with around 200 trials. It estimates that the number of clinical trials being conducted is between 800 and 1000 and is growing at 15% per annum.

One risk going forward with Cryosite is whether it is able to renew a five-year contract it has had with American Type Culture Collection.

Cochlear			CMP	\$53.97
COH	Cap'n (\$M)	\$3,014	PE	26
	FY2005	FY2006	FY2007	FY2008
Sales (\$M)	\$349.0	\$452.3	\$556.2	\$600.1
Change		30%	23%	8%
EBIT (\$M)	\$85.24	\$115.23	\$153.58	\$162.63
Change		35%	33%	6%
Net Profit (\$M)	\$58.48	\$78.23	\$97.68	\$115.23
Change		34%	25%	18%

Compumedics			CMP	\$0.17
CMP	Cap'n (\$M)	\$24	PE	31
	FY2005	FY2006	FY2007	FY2008
Sales (\$M)	\$38.4	\$37.7	\$36.7	\$38.6
Change		-2%	-3%	5%
EBIT (\$M)	-\$4.68	-\$1.60	\$0.99	\$1.40
Change		NA	NA	41%
Net Profit (\$M)	-\$4.68	-\$1.60	\$0.12	\$0.76
Change		NA	NA	515%

Cryosite			CMP	\$0.13
CTE	Cap'n (\$M)	\$6	PE	14
	FY2005	FY2006	FY2007	FY2008
Sales (\$M)	\$2.8	\$4.1	\$4.7	\$6.6
Change		45%	15%	41%
EBIT (\$M)	\$0.11	-\$0.63	\$0.38	\$0.46
Change		NA	NA	19%
Net Profit (\$M)	\$0.10	-\$0.63	\$0.99	\$0.45
Change		NA	NA	-55%

CSL – A stellar performance

CSL, Australia's largest pharmaceutical firm and 14th largest ASX-listed company, drove a 30% lift in net profit to \$702 million, from sales of \$3.6 billion. Domestic sales of Gardasil were a significant component of this result, with local sales of \$227 million reported. Local sales are expected to decline in FY2009 as a schools-based catch up program is expected to complete by the end of CY2008. CSL expects FY2009 sales of Gardasil to be in the order of \$100 million. Gardasil royalties received from Merck revenues were \$167 million for FY2008. CSL expects FY2009 royalties for Gardasil to be in the order of \$180- \$200 million.

Sales for CSL's largest division, CSL Behring were \$2.822 billion (US\$2.5 billion), and rose 15% in constant currency terms.

CSL has now completed expansion at its Melbourne flu vaccine plant to produce 40 million doses per season (there are two per year), with the company's US branded flu vaccine Affluria now approved for sale by the FDA.

Ellex Medical Lasers – Disappointing result

Adelaide-based Ellex Medical Lasers manufactures lasers for ophthalmic surgery. The company logged a 13% growth in sales for FY2008, with \$50.3 million achieved for the year. The company posted a net profit of \$4.8 million, but adjusted for on-offs, was \$1.1 million (previous year – \$4.4 million and adjusted \$2.5 million). The 'one-offs' related to deferred tax assets. However, the company was disappointed with the result, and especially that its investment in sales and marketing activities in the US did not pay off to the degree expected. US sales increased 10%, in contrast to sales growth in Australia (36%), Japan (25%) and Europe (17%). The company also suggested that the credit crisis had a negative impact on the short term buying decisions of its customers.

Ellex's employee costs increased 30% , from \$12.5 million in FY2007 to \$16 million in FY2008. Ellex now employs six direct sales staff in the USA in addition to 10 independent representatives.

IDT Australia – Expanding the business

IDT Australia provides services to the global drug development industry in addition to highly specialised API (active pharmaceutical ingredient) and finished dose manufacturing. Sales for FY2008 increased 18% to \$31.5 million and the company posted a net profit of \$7.1 million (+30%).

The company announced a final dividend of \$6.5 cents, which with the half year dividend of 5.5 cents has the stock offering a yield of 5.6%.

Growth prospects for the company auger well for IDT following the commissioning of 4000 litre facility developed in conjunction with Pfizer. The company expects to deliver strong double digit profit growth in FY2009.

CSL			CMP	\$39.43
CSL	Cap'n (\$M)	\$23,589	PE	34
	FY2005	FY2006	FY2007	FY2008
Sales (\$M)	\$2,609.0	\$2,848.9	\$3,172.4	\$3,556.7
Change		9%	11%	12%
EBIT (\$M)	\$432.2	\$515.0	\$918.7	\$1,108.4
Change		19%	78%	21%
Net Profit (\$M)	\$487.8	\$117.4	\$539.3	\$701.8
Change		-76%	359%	30%

Ellex Medical Lasers			CMP	\$0.26
ELX	Cap'n (\$M)	\$18	PE	16
	FY2005	FY2006	FY2007	FY2008
Sales (\$M)	\$27.0	\$34.6	\$44.4	\$50.3
Change		28%	28%	13%
EBIT (\$M)	\$1.21	\$4.20	\$3.34	\$2.51
Change		248%	-20%	-25%
Net Profit (\$M)*	\$0.63	\$3.69	\$2.52	\$1.11
Change		487%	-32%	-56%

* adjusted for FY07,FY08

IDT Australia			CMP	\$2.15
IDT	Cap'n (\$M)	\$93	PE	13
	FY2005	FY2006	FY2007	FY2008
Sales (\$M)	\$26.9	\$25.0	\$26.7	\$31.5
Change		-7%	7%	18%
EBIT (\$M)	\$5.36	\$5.12	\$7.86	\$10.18
Change		-4%	53%	29%
Net Profit (\$M)	\$3.34	\$3.62	\$5.47	\$7.11
Change		8%	51%	30%

ITL Corp – A poor result

ITL Corp sells and manufactures medical devices and medical procedure kits. The company recorded sales of \$38.2 million, up 9% from the previous year. The company's profitability has slumped over the last two years, with the result for FY2008 of \$0.8 million down 56% from the FY2007, and the FY2007 result down 46% from the FY2006 figure.

Australian operations generated sales of \$15.6 million, down from \$16.7 million in FY2007. The company also said its Malaysian healthcare business was seriously impacted by the downturn in large medical infrastructure projects in Malaysia. ITL is hoping that staff cuts and new a new business information system will contribute to an improved performance.

Probiotec – A strong result

Probiotec is a manufacturer of branded OTC and prescription products. It also provides contract manufacturing services. The company's brands include the Biosource supplements lines, the Medislim weight loss lines, the Milton antibacterial range, and the David Craig brand for pharmacy products. The company is headquartered in Laverton, but also operates facilities in Nowra, Bundaberg and Malanda.

Probiotec generated a strong result for FY2008, with sales increasing 22% to \$65.8 million. Sales in the pharmaceutical and consumer health segment rose by 43% for FY2008 (\$48.7 million). Net profit of \$6.3 million rose 27% for the period. Normalised net profit grew 60.3%. Gross profit margins increased 5.3% to 42.7%. However, the company has relatively high debt levels, with gearing at 52%.

New product development is a key plank for growth at Probiotec, with the company investing \$1.9 million in new product development in FY2008. The company employs 50 people in QC and product development and 500 people in total.

The company has signalled that it expects that net profit to grow by at least 20% in the next year.

Resmed – Continuous product development

Sleep-disordered breathing company Resmed generated sales of US\$835 million for FY2008, up 17% from the previous year. (Resmed is a US company that was founded in Australia (1989) and maintains manufacturing facilities in Sydney. The company's shares trade as depository receipts on the ASX.) However, when movements in US currency are taken into account sales increased by 11%.

Resmed posted a net profit US\$110 million, which represented an increase 66% from the previous year. (FY2007 results were impaired by a product recall.) Sales in North and Latin America increased 9% for the year, and sales outside these area increased by 25%. New product development is a major theme of the Resmed growth argument, with two new masks, the Micro Mirage and the Swift LT, and new instruments, the CPAP S8 Autoset II and the VPAP Auto introduced this year.

ITL Corp			CMP	\$0.09
ITD	Cap'n (\$M)	\$12	PE	16
	FY2005	FY2006	FY2007	FY2008
Sales (\$M)	\$21.2	\$31.3	\$35.0	\$38.2
Change		47%	12%	9%
EBIT (\$M)	-\$0.48	\$3.88	\$2.44	\$1.43
Change		-901%	-37%	-41%
Net Profit (\$M)	-\$0.03	\$3.26	\$1.74	\$0.76
Change		-10122%	-46%	-56%

Probiotec			CMP	\$1.35
PBP	Cap'n (\$M)	\$63	PE	10
	FY2005	FY2006	FY2007	FY2008
Sales (\$M)	\$26.0	\$41.5	\$54.0	\$65.8
Change		60%	30%	22%
EBIT (\$M)	-\$4.28	\$4.13	\$7.66	\$10.41
Change		NA	85%	36%
Net Profit (\$M)	-\$2.83	\$1.81	\$4.98	\$6.31
Change		NA	176%	27%

Resmed			CMP	\$5.41
RMD	Cap'n (\$M)	\$4,186	PE	32
	FY2005	FY2006	FY2007	FY2008
	US\$	US\$	US\$	US\$
Sales (\$M)	\$425.5	\$607.0	\$716.3	\$835.4
Change		43%	18%	17%
EBIT (\$M)	\$97.43	\$132.07	\$104.45	\$167.91
Change		36%	-21%	61%
Net Profit (\$M)	\$64.79	\$88.21	\$66.30	\$110.30
Change		36%	-25%	66%

Sirtex Medical – Marketing costs impact bottom line

Sirtex Medical markets Sir-Spheres, a treatment for liver cancer. After reporting strong growth in sales for FY2007 (+48%, \$33 million), growth fell back in FY2008 to 14%, with an end year result of \$38 million. Appreciation of the AUD against the USD impacted Sirtex's sales, which increased 22.5% on a volume basis.

Sirtex's profit fell 23%, with the company increasing marketing costs from \$9.8 million in FY2007 to \$16 million in FY2008.

Sirtex expects costs in the order of \$5.5 million pertaining to its litigation with UWA and Dr Bruce Gray to be recovered. It is uncertain when this recovery might take place. The company held cash of \$7 million at the close of the financial year and was essentially debt-free.

Summary

Not covered were Arana Therapeutics, which has a September 30 end of financial year and SDI, Blackmores and Medical Developments. In short, 17 profitable life science companies are listed on the ASX.

Some companies moving towards profitability include Biota Holdings, Cogstate, Atcor Medical, Acrux, Labtech Systems and Somnomed.

Sirtex Medical			CMP	\$2.20
SRX	Cap'n (\$M)	\$123	PE	101
	FY2005	FY2006	FY2007	FY2008
Sales (\$M)	\$11.8	\$22.6	\$33.3	\$38.1
Change		91%	48%	14%
EBIT (\$M)	-\$1.99	\$5.46	\$4.33	\$2.50
Change		NA	-21%	-42%
Net Profit (\$M)	-\$2.00	\$1.81	\$1.57	\$1.21
Change		NA	-13%	-23%

Bioshares

Tissue Therapies – A Positive Result

Tissue Therapies (TIS: SP 13 cents; Cap \$5 M) has delivered the first result from a clinical treatment using its wound healing technology, Vitrogro. One patient who had a venous leg ulcer that had not been healing for several months experienced a 60% reduction in the wound area within 21 days, after only four applications of the Vitrogro product. It was a spectacular result and consistent with preclinical studies.

Not only was there a large reduction in the immediate wound size, but the surrounding area clearly looked to have improved.

The issue for Tissue Therapies is how it will commercialise the technology. Clinical trials in Canada (in 30 patients) were expected to start last year and the company is still awaiting approval to proceed from Health Canada. In the meantime the company is conducting a clinical trial in Australia in eight patients, which is expected to be completed by year's end.

The appeal of gaining approval in Canada is that there is mutual recognition with other regulators, including the TGA in Australia and most of Europe. However it appears that quite a few other groups are following a similar pathway, a possible explanation for the regulatory delay from Canada to proceed with trials.

Whilst the technology is compelling, the company is constrained by its access to funding. We estimate the company will have just over \$1 million following the recently completed share purchase

plan. The company is looking at raising additional funds from sophisticated investors.

The wound healing market is massive. However, the challenges for a small biotech with very limited cash resources to access this market are becoming obvious. Tissue Therapies will need to license the technology or merge with a larger group to gain greater leverage.

Bioshares recommendation: **Speculative Buy Class C**

Bioshares

Bioshares Model Portfolio (5 September 2008)			
Company	Price (current)	Price added to portfolio	Date added
Impedimed	\$0.75	\$0.70	Aug-08
Antisense Therapeutics	\$0.07	\$0.07	Aug-08
Mesoblast	\$1.14	\$1.25	Aug-08
Avexa	\$0.29	\$0.32	Jun-08
Cellestis	\$2.19	\$2.27	April 2008
IDT	\$2.15	\$1.90	March 2008
Circadian Technologies	\$0.83	\$1.03	February 2008
Patrys	\$0.25	\$0.50	December 2007
NeuroDiscovery	\$0.09	\$0.16	December 2007
Bionomics	\$0.35	\$0.42	December 2007
Cogstate	\$0.14	\$0.13	November 2007
Sirtex Medical	\$2.20	\$3.90	October 2007
Clinuvel Pharmaceuticals	\$0.29	\$0.66	September 2007
Starpharma Holdings	\$0.24	\$0.37	August 2007
Pharmaxis	\$2.32	\$3.15	August 2007
Universal Biosensors	\$0.78	\$1.23	June 2007
Biota Holdings	\$0.78	\$1.55	March 2007
Probiotec	\$1.35	\$1.12	February 2007
Peplin Inc	\$0.45	\$0.83	January 2007
Arana Therapeutics	\$1.11	\$1.31	October 2006
Chemgenex Pharma.	\$0.93	\$0.38	June 2006
Cytopia	\$0.22	\$0.46	June 2005
Optiscan Imaging	\$0.23	\$0.35	March 2005
Acrux	\$1.10	\$0.83	November 2004
Alchemia	\$0.30	\$0.67	May 2004

Portfolio Changes – 5 Sept 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, NeuroDiscovery, 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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