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Biosharesv

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

Strong Growth For Revenue Generating Biotechs While Currency Headwinds Stiffen

Most cash generating life science companies in Australia derive the majority of their income from overseas. When the Australia dollar fell heavily last year, it delivered a surprising bonus for these businesses with accelerated profitability. However, now with the dollar appreciating significantly, particularly against the US currency, the strength of these businesses is being tested.

Sirtex Medical

Sirtex Medical (SRX: $6.20) has seen a very strong rally in its share price this year with no signs of slowing. The company has firmly moved into profitability, generating a net profit for FY2009 of $18.2 million. Over the last two quarters receipts from customers have fallen due to the appreciating Australian dollar, from $21.1 million in the March quarter, to $17.5 million in the June quarter to $16.4 million in the last quarter.

Growth in Unit Sales The Measure to Watch

However, over the last year, receipts from customers have increased by 59% in the September quarter over the previous corresponding period. The most important metric to monitor is growth in unit sales, which increased to 1,018 units over the pcp, a 27% change. Sirtex receives on average $16,000 per treatment. It currently has an effective monopoly with its liver cancer irradiation therapy.

The strongest growth is currently being seen in Europe, where sales increased by 70%. There are now 68 centres applying the Sirtex SIR-Spheres treatment to patients with cancer that has spread to the liver. In the US, growth had slowed to 16%.

The driver in sales will come from increased familiarity with performing the SIR-Sphere treatment, and from expanding indications for the treatment and use in first stage therapy. Currently Sirtex is sponsoring 15 clinical trials, including use of the therapy for treatment of primary liver cancer for which it does not have approval in major markets (only for treatment of cancer metastases that spread from colon cancer), for treatment as a first line therapy with FOLFOX chemotherapy in cancer that has spread from the colon to the liver, and also in cancer that has spread to the liver from neuroendocrine tumours.

Dividend Announced

In the most recent quarter, the company generated sales of $16.5 million with an operating profit of $5.47 million. Sirtex is currently capitalised at $346 million. Based on its latest quarter operating profit, the company is currently trading on a PE ratio of around 22 times. It recently announced its first dividend payment of 7 cents per share (including a 5 cent special dividend).

Sales and profit growth is expected to show strong and consistent growth, making Sirtex a long term growth stock. Stockbroking firm Taylor Collison expects sales to increase to

Cont'd over

In this edition...

The talking point for many investors is "Whither the US dollar?" with AU$1.00 buying US$0.92. Quite a number of revenue generating biotechs have seen top line weakness in revenue as US earnings have been converted back into Aussie dollars.

While no one knows where the US dollar is really headed, the key point for investors is to monitor earnings in local currencies or in volume sales. With a number of the emerging revenue earners such as Sirtex Medical and Cogstate (or their partners, as with Labtech Systems and Biomerieux) selling product at an early stage of the adoption curve, we can expect these companies over the longer term to continue to perform well.

The Editors

Companies Covered: ACG, CGS, LBT, 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)	69.6%
Cumulative Gain	**229%**
Av Annual Gain (9 yrs)	**20.8%**

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$139 million over the next three years with a net profit of $42 million forecast for FY2012. Whilst the appreciating Australian dollar is having an impact on top and bottom line growth, the strength of the underlying business should continue to generate impressive results.

Bioshares recommendation: **Buy**

Cogstate – Strong Growth Continues

For Cogstate (CGS: $0.31), which delivers cognitive testing services to mainly US-based pharmaceutical companies in clinical trials, the company is on track to continue to deliver solid top and bottom line growth given the high growth phase in its business cycle.

Double-digit growth anticipated

In local currency terms, the company is forecasting sales growth for the first half of this financial year of 23% over the previous corresponding period (pcp), to $4.75 million (or 43% growth in USD, which better reflects the growth of the underlying business). Its operating profit in this six months is expected to be as high as $0.96 million (bottom of forecast range is $0.73 million), which will represent just under a 130% growth over the pcp at the high end of its forecast (74% growth at the bottom forecast end).

Continued strong growth in Cogstate's business can be attributed to further acceptance by pharmaceutical companies of computerized cognitive testing, and the increasing reputation and awareness of the Cogstate product. In the last two years, Cogstate has grown its sales from only $2.2 million in FY2007 to $8.4 million. In the 2009 financial year, Cogstate signed less contracts whilst increasing revenue by 120% to $8.4 million, reflecting the larger average contract size ($289,000 compared to $123,000 in FY2008).

Cogstate has a very strong scientific team that underpins its technology. That team now includes Dr John Harrison, who developed the NTB test (Neuropsychological Test Battery) which has been used by **Elan** and **Wyeth**, two major companies in the Alzheimer's disease area, and also local company **Prana Biotechnology**. The NTB test has been incorporated into the Cogstate business and Cogstate is the only licensed distributor of this test.

We expect revenue for the current financial year will exceed $10 million. The Global Financial Crisis ended affected the spending patterns of pharmaceutical companies, with the period between September 2008 and February 2009 being a quiet period for Cogstate in signing new contracts. However spending patterns appear to have returned to normal. In the first quarter of this financial year, the company signed contracts worth $3.7 million. (Note that last year recognised sales represented 90% of contracts signed over that year. While Phase I trials take only around 6 months to complete, Phase II trials take around two years to complete.)

In the last financial year, the company weathered a failed business relationship with a larger pharmaceutical services provider, **United BioSource Corporation**. UBC sold its 16% stake in Cogstate this year to Australian institutional investors, with whom the company is now generating good investment interest. UBC has since acquired one of Cogstate's competitors, **Cognitive Drug Research**.

Clinical Trial Services Provide Solid Base for Growth

We expect Cogstate will continue to generate strong sales growth which will allow profitability to continue to grow even with an appreciating Australian currency. With the clinical trial service business now on a firm footing, generating an annual operating of around $2 million a year, it also allows the company to consider expanding the applications of its proprietary cognitive testing technology into other areas. For a company capitalised at $21 million (66 million shares) that is at an inflexion point of its business, Cogstate represents an attractive investment option that no longer falls into the speculative investment class.

Bioshares recommendation: **Buy**

Bioshares

Tyrian Diagnostics– Update

Tyrian Diagnostics (TDX: 1.8 cents) and **Becton Dickinson** have ended their TB diagnostic collaboration. In the end, BD was unable to develop a suitable point-of-care (POC) diagnostic that would accurately detect Tyrian Diagnostic's novel TB biomarker.

Tyrian will now continue with a molecular RNA-based TB diagnostic program with Dr Barry Kreiswirth at the **Public Health Research Institute TB Centre** in New Jersey. The focus will be initially to develop the RNA-based POC test, then moving on to a second generation protein-based POC test.

BD tested four platforms, including the Tyrian diagnostic hardware. However, each was not sensitive enough not detect the TB biomarker. Tyrian will also focus on developing other respiratory disease POC tests.

Tyrian will shortly select a contract manufacturer in Asia to make its ReadRite point-of-use test for assessing wheat quality, which is being sold and marketed by **Bayer** (Germany). It is expected the facility will be able to make sufficient quantities for demand from Bayer by the end of March next year.

Tyrian is working on a second crop test product for Bayer, with 3,000 prototypes already having been supplied. The market is expected to be similar in size to the wheat test, conservatively generating over $30 million a year for Bayer. Tyrian will also receive a single digit royalty plus a manufacturing margin from the product. Tyrian will also receive product development fees. This second product may reach the market in 2010.

By the first quarter of next year, Tyrian expects its burn rate will have been reduced to $4 million a year. The company now has 22 employees. Last year the company generated $1.3 million in revenue and receipts from customers in the current quarter totalled $313,000. The company had $6.4 million in cash at the end of September and is capitalised at $9 million.

Bioshares recommendation: **Speculative Hold Class B**

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Atcor Medical Aims for CPT Filing in 2010

The Atcor Medical (ACG: $0.18) AGM, held in Sydney this week, offered shareholders the opportunity to review the progress of a company that is building cash flows and a company that has also not needed to raise funds from shareholders since it listed in 2005.

Atcor Medical markets the Sphygmocor device, which is used to non-invasively measure central blood pressure, as opposed to the measurement at the cuff (e.g. arm, extremity).

Numerous studies have been conducted and published that demonstrate the superiority of measuring central blood pressure both for its predictive powers and the improved accuracy it provides.

Atcor CEO Duncan Ross listed several studies completed by researchers during FY2009. In one study of 800 patients, the Sphygmocor technology was found to be a predictor of first onset atrial fibrillation (an electrical problem of the heart). Existing technologies can detect but not predict AF and this finding would appear to open up a new application area for the diagnostic technology.

In a 2,405 patient study examining the condition of hypertension, the Sphygmocor technology was used to discover that central pulse pressure of greater than 50 mm of mercury was a significant indicator of cardiovascular events. This finding, which will be published in the *Journal of American College of Cardiology* this month.

Ross also reported that the Sphygmocor technology may be effective in predicting pre-eclampsia in the first tri-mester of pregnancy, and another study that showed the technology can be applied to measuring elevated central pressure in African Americans. (African Americans have a genetic disposition to high blood pressure, and the drug Bidril was developed with that specific genetic segment.)

Financial Position and FY2010 Outlook

Atcor Medical locked in sales of $11.2 million but recorded a loss of $1.7 million for FY2009.After posting sales growth in constant currency terms of 47% for FY2009, the company is forecasting strong double digit sales growth for FY2010, with the second half expected to be stronger than the first half. Atcor held cash of $2.2 million as of September 30, 2009. The company holds no debt. The balance of outstanding loans were repaid to the company in October.

A substantial component of Atcor's income is derived from sales of Sphygmocor related services (including the WISDOM clinical trial data management system) to pharmaceutical firms conducting clinical trials. The company stated it was in negotiation with four drug firms, with anticipated revenue, assuming contracts are signed, to flow in H2 FY2010.

US Reimbursement Progress

A potential major milestone for Atcor Medical in 2010 will be the filing of submission with the **American Medical Association** to obtain a specific code for Sphygmocor-based measurements, which would then be used in establishing pricing and gaining reimbursement where the device is used to conduct measurement in medical use beyond the research setting. The submission may be made in November (there are three submission periods each year). The code, if granted, should then be effective from Jan 1, 2011.

A Current Procedural Terminology (CPT) Category 1 code means that Atcor Medical can expand the rollout of the Sphygmocor approach to measurement into the much larger general practitioner (primary care physician) market where income can be generated from each measurement procedure.

Achieving a CPT code depends on solid medical evidence. Given that several hundred papers have been published on central blood pressure measurement as is delivered by the Sphymocor technology, gaining a CPT code on that count looks achievable.

However, the AMA has five criteria for granting a new code. The product or service must be approved by the FDA; it must be a distinct procedure or service performed by many physicians; clinical evidence of the service or procedure must be well established and documented; the service or procedure must not be a fragment of an existing code and not currently reportable by an existing code; and finally the service or procedure must not be ‘a means to report extraordinary circumstances related to the performance of a procedure/service already having a specific CPT code’.

A potential challenge for the company may be in marking out the Sphygmocor approach to blood pressure as ‘new and substantially different’ to current blood pressure testing at the cuff. However, it is more likely that a code will be granted for where the technology has been shown to be a novel and effective way to aid clinical assessment.

The company has retained consultants in the US to assist with the coding and coverage process. Coverage refers to gaining acceptance from insurance companies of which there are hundreds which are often local in geographic exposure with only a few companies being largely national. Typically coding, coverage and payment are issues equally important for the commercial success of new products and services used in the US healthcare system.

Commentary

Although Atcor Medical may be one of a group of Australian life science companies that will see sales figures tempered while the Australian dollar appreciates against the US dollar, investors should continue to remain cognisant of the global opportunity for the Sphygmocor technology and also recognise that acceptance of central blood pressure measurement is still at an early phase on the adoption curve.

In time, gaining a unique reimbursement code in the USA may be one of several events that will enable the company to move into the next level of revenue opportunity. Another blue-sky prospect is that a new medicine developed with the aid of the Sphymocor device is approved on the basis the device is used with the drug. Atcor Medical is capitalised at $18 million.

Bioshares recommendation: **Speculative Buy Class A**

Labtech Systems Receives First Royalty Payment

LabTech Systems (LBT: $0.14) has received its first royalty payment of $111,350 from its partner **BioMerieux**. The royalties relate to the Microstreak applicator, which is used to streak agar plates that are processed in an automated microbiology instrument developed by Labtech Systems and marketed by Biomerieux as the PREVI Isola system. Labtech Systems receives a double digit royalty from the sale of these applicators, although the company can receive a minimum royalty for CY2010 of US$240,000.

The receipt of a further milestone payment from BioMerieux of approximately $3.4 million is anticipated in April 2010. This payment would place the company in a comfortable position while it continues to explore new product development opportunities in its area of expertise.

The company has not only executed on developing a solution to workflow and productivity challenges in the microbiology labs of central testing laboratories, but has also developed project management expertise in working with instrument designers and builders, and in securing a marketing partner. The company's achievement to date has been significant and has established the credibility that gives investors confidence.

The company is well placed to take on new product development goals. If and when the company selects a new project it may bring in further investment to support the task. However, this may depend on the rate that the PREVI Isola instruments are being installed around the world and on the rate that the applicator plates are used by instrument users. It is expected that in time BioMerieux will increase the supply of PREVI Isola instruments by adding manufacturing capacity in other locations. (The machines are currently made in Melbourne.)

The company reported cash holdings of $2.8 million as of September 30, 2009. Labtech Systems is capitalised at $14 million.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

Correction:
In our report from the Wilson HTM Life Science conference, in the section on Starpharma, the sentence

'There are no other microbicides in clinical development according to SSL.'

should have read

'SSL and Starpharma believe there are no other condoms coated with microbicide agents in development.'

Bioshares Model Portfolio (23 October 2009)

Company	Price (current)	Price added to portfolio	Date added
Biodiem	$0.19	$0.15	October 2009
QRxPharma	$1.15	$0.25	December 2008
Hexima	$0.71	$0.60	October 2008
Atcor Medical	$0.18	$0.10	October 2008
CathRx	$0.60	$0.70	October 2008
Impedimed	$0.78	$0.70	August 2008
Mesoblast	$1.05	$1.25	August 2008
Circadian Technologies	$0.74	$1.03	February 2008
Patrys	$0.13	$0.50	December 2007
Bionomics	$0.28	$0.42	December 2007
Cogstate	$0.31	$0.13	November 2007
Sirtex Medical	$6.20	$3.90	October 2007
Clinuvel Pharmaceuticals	$0.33	$0.66	September 2007
Starpharma Holdings	$0.55	$0.37	August 2007
Pharmaxis	$2.61	$3.15	August 2007
Universal Biosensors	$1.75	$1.23	June 2007
Probiotec	$2.65	$1.12	February 2007
Chemgenex Pharma.	$0.76	$0.38	June 2006
Acrux	$1.96	$0.83	November 2004
Alchemia	$0.54	$0.67	May 2004

Portfolio Changes – 20 October 2009

IN:
No changes.

OUT:
No changes.

How Bioshares Rates Stocks

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

Group A

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

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

(CMP–Current Market Price)

Group B

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

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

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

Speculative Buy – Class C
These stocks generally have one product in development and lack many external validation features.

Speculative Hold – Class A or B or C

Sell

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