

**In this edition...**

The levee that has supported a high Australian dollar has broken its banks, sending flood waters towards the parched soils of Australia's exporters. We have calculated the pre-tax contribution to bottom line results for eight medical product exporters (or foreign income recipients) from a drop in the Aussie dollar from \$1.03 to \$0.92 against the US dollar. Uscom, the non-invasive central blood flow measurement company has added non-invasive central blood pressure measurement to its product offerings, through the acquisition of Pulsacor from New Zealand. Investors will do well to monitor sales from its relatively recently FDA approved Cardioscope BP+ device, over the next twelve months.

**Companies Covered: ACG, ACL, ACR, CGS, NAN, SOM, SRX, UBI, UCM**

	Bioshares Portfolio
Year 1 (May '01 - May '02)	21.2%
Year 2 (May '02 - May '03)	-9.4%
Year 3 (May '03 - May '04)	70.6%
Year 4 (May '04 - May '05)	-16.3%
Year 5 (May '05 - May '06)	77.8%
Year 6 (May '06 - May '07)	17.4%
Year 7 (May '07 - May '08)	-36%
Year 8 (May '08 - May '09)	-7.4%
Year 9 (May '09 - May '10)	50.2%
Year 10 (May '10 - May '11)	45.4%
Year 11 (May '11 - May '12)	-18.0%
Year 12 (May '12 - May '13)	3.1%
Year 13 (May '13 - Current)	2.2%
<b>Cumulative Gain</b>	<b>264%</b>
<b>Av. annual gain (12 yrs)</b>	<b>16.6%</b>

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

Enquiries for *Bioshares*  
Ph: (03) 9326 5382  
Fax: (03) 9329 3350  
Email: info@bioshares.com.au

**David Blake - Editor**  
Ph: (03) 9326 5382  
Email: blake@bioshares.com.au  
**Mark Pachacz - Research Principal**  
Ph:(03) 9348 9317  
Email: pachacz@bioshares.com.au

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# Bioshares

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

## FX Effects for Australian Biotechs

In the last two months, the Australian dollar has fallen from \$1.03 to \$0.92 against the US dollar. With many companies in the sector now generating significant revenue denominated in US dollars, its very positive news with the US currency appreciation showing no signs of abating. Below we look at the impact the currency movement will have on eight Australian medical product companies.

### Cogstate

Cogstate is on track to deliver revenue this financial year of between \$11-\$12 million. We expect the company will record a loss of between \$1-\$1.5 million, largely due to the investment the company is making in new product applications in dementia screening and concussion management in Canada and the US respectively.

According to Cogstate CEO Brad O'Conner, all of the company's revenue (outside of Australia) is denominated in USD. A 15 cent fall in the Australian dollar from parity to \$0.85 against the US dollar is expected to result in \$3 million more of sales and an increase in net profit of around \$1 million for the company.

### Sirtex Medical

On annualised half year numbers, Sirtex Medical is generating annual sales of \$92 million with a net profit of \$15.7 million. Sales are up 25% on the previous corresponding half and profit is up 34%.

For Sirtex Medical, around 70% of its earnings are in US dollars and 25% are denominated in Euros. According to CFO Darren Smith, a fall in the Australian dollar from \$1.03 to \$0.90 would result in a \$6 million benefit to earnings before tax.

### Nanosonics

We are forecasting Nanosonics to generate sales of \$13.8 million this financial year, and increasing to \$24 million in FY2014 based on an exchange rate of \$0.92 against the US dollar.

*Cont'd over*

## The 9<sup>th</sup> Bioshares Biotech Summit

July 19-20, 2013 · Queenstown · New Zealand

### **The Essential Australian Biotech Investment Event**

#### Speakers include...

Jackie Fairley (CEO, Starpharma), Paul Wright (CEO, Universal Biosensors), Robert Crane (CFO, GI Dynamics), Neil Verdal-Austin (CFO, Somnomed), Mike McCormick (CEO, Osprey Medical), Brad O'Connor (CEO Cogstate), Greg Collier (CEO, Invion) and many more.

[www.bioshares.com.au/queenstown2013.htm](http://www.bioshares.com.au/queenstown2013.htm)

Nanosonics generates 83% of its revenue from North America. A 10% fall in the Australian dollar against the greenback adds around \$1 million to the company's earnings before tax. Nanosonics is moving towards a cash flow positive position. An extra \$1 million to its bottom line may see the company cross the line into the black six months earlier with a 10% drop in the Australian dollar against the US currency. Nanosonics manufactures in Australia and has a small sales force in the US with 9 staff in total, which assists its partner GE Healthcare with sales.

### Atcor Medical

We expect Atcor Medical to generate sales of \$8 million this financial year. Atcor Medical generates between 90%-95% of its revenue off-shore. About 40% of the company's costs are in the US, 50% in Australia, and about 10% in Europe where there is a natural currency hedge from sales. Assuming that 90% of sales are generated in the US, it should deliver the company an extra \$1 million in sales for the year, based on current sales levels with a currency movement from \$1.03 to \$0.92. It will also help the company remain cash flow positive, with the company expected to achieve its fourth consecutive quarter of positive cash flow this month. The increased \$1 million in sales should see around \$400,000 extra flow through to the bottom line by our calculations.

### Alchemia

Alchemia's revenue is almost entirely based on US sales of the generic blood thinning drug fondaparinux in the US. Based on the peak sales numbers announced in February, Alchemia stands to receive a profit share of \$12.6 million at current exchange rates, which is \$1 million more than if the Australian dollar was at parity with the US dollar.

### Universal Biosensors

Universal Biosensors (UBI) generated revenue of \$30 million last year, with all of its contracts denominated in US currency. Of this revenue, 82% came from its contracts with Lifescan and 16% of revenue from its Siemens development collaboration. The most important revenue stream for UBI is the US1 cent (approximately) per strip service revenue that it receives from Lifescan for each of the Verio glucose test strip that Lifescan sells globally.

An estimated \$16 million of revenue over this calendar year at an

### Impact of AUD/USD exchange rate on Selected Companies

Company	Sales for AUD/USD = \$1.03 (\$M)	Sales for AUD/USD = \$0.92 (\$M)	Improvement in bottom line result before tax
Acrux (forecast royalty & milestones FY2014)	\$53.4	\$60.0	\$6.6
Alchemia (forecast profit share FY2014)	\$12.6	\$13.6	\$1.0
Atcor Medical (FY2013e)	\$8.0	\$9.0	\$0.4
Cogstate (FY2014e)	\$13.0	\$14.6	\$0.5
Nanosonics (FY2014e)	\$21.6	\$24.2	\$1.4
Sirtex Medical (FY2013e)	\$92.0	\$100.0	\$5.2
Somnomed (FY2014e)	\$22.0	\$23.6	\$1.0
Universal Biosensors(FY2014e)	\$16.0	\$17.9	\$1.9

exchange rate of \$1.03 increases to \$17.9 million when the Australian dollar is worth 92 cents against the US dollar.

### Acrux

Acrux receives royalty and milestone payments from Eli Lilly for sales of the transdermal testosterone drug Axiron. Sales of Axiron are largely generated in the US. In the March quarter, Axiron net sales were \$37.1 million, up 55% over the December quarter. If net sales reach US\$200 million in FY2014, then based on an estimated royalty of 15%, Acrux should receive royalties of \$32.8 million based on the current exchange rate, which is \$2.8 million more than when the currency was at parity.

Acrux also expects to receive a milestone payment of US\$25 million for this calendar year, which will now be worth \$27.2 million in Australian currency at current exchange rates.

### Somnomed

Somnomed generates an estimated 60% of its revenue from North America. Based on estimated sales next financial year of \$22 million, we estimate \$13 million comes from the US. A strengthening of the US dollar from AUD/USD \$1.03 to \$0.90 should deliver increased sales of about \$1.6 million, increasing our sales forecasts next year from \$22 million to just under \$24 million based on an AUD/USD exchange rate of \$0.92. This should also translate to an estimated extra \$1.0 million flowing through to the bottom line in FY2014.

### Positive Translation Benefit

For some of these companies, there will also be a positive currency translation benefit from cash being held in US dollars. In 2012, Sirtex had a translational loss of \$429,000 added to its bottom line due to the appreciating Australian dollar.

### Summary

The strengthening US dollar is very good news for many Australian biotechs that have US dollar earnings. For those companies approaching profitability means that point will be achieved sooner. This applies to Cogstate, Atcor Medical, Alchemia and Nanosonics.

Another factor with an appreciating US dollar is that it increases the likelihood of acquisitions of Australian biotechs, which are currently 11% cheaper than they were at the start of May. The acquisition targets are not only the revenue earners, but also those biotechs in the development phase. Potential acquisition targets include: Nanosonics, Sirtex Medical, Pharmaxis, Somnomed and Universal Biosensors

Bioshares

## **Uscom Acquires Pulscor to Merge Central Blood Flow Measurement with Central Blood Pressure Measurement**

On June 18, Uscom (UCM:\$0.20) completed its acquisition of Pulsecor, a New Zealand company which has been commercialising novel blood pressure and cardiovascular health assessment devices which use suprasystolic oscillometry as the core technology.

Pulsecor's lead device is the Cardioscope BP+. This is a market ready product, priced at US\$3,500. However, sales have yet to be initiated on a comprehensive basis. The device has a CE Mark, and is FDA (Nov 2012) and TGA approved.

### **Predicate Devices**

The predicate devices cited in Pulsecor's 510(k) application for the Cardioscope BP+ included Healthstats International Pte Ltd A-PULSE CasPro, Atcor Medical's SphygomCor Px and I.E.M GmbH's Monil-O-Graph PWA.

### **Expansion of Product Range**

The newly acquired technology and products will sit alongside Uscom's non-invasive cardiac output monitor, the USCOM 1a, which sells for US\$30,000. This device measures blood flow across the heart valves using Doppler ultrasound. According to Uscom, it is the 'only truly non-invasive, accurate system of hemodynamic measurement'.

### **The Acquisition**

The acquisition was funded through the issue of 5 million Uscom shares at a 50 cent share price, at a valuation of \$2.4 million. PulseCor was last valued at \$2.4 million in 2011, prior to its receipt of FDA approval for the Cardioscope BP+ in 2012.

The acquisition also includes 34 patents and patent applications, (presumably) including the US granted patent 'Non-invasive measurement of suprasystolic signals' (7,727,157) (expires 2030) and US patent application 'Non-invasive measurement of suprasystolic signals' (20100256507). The inventor named on these patents is Dr Nigel Sharrock, who will be joining the USCOM Medical Advisory Board. Sharrock is Clinical Professor of Anesthesiology, Weill Cornell Medical College in New York. He graduated from the University of Otago's Medical School in 1971.

Pulsecor was founded by Nigel Sharrock and engineer Andrew Lowe in 2004.

### **How the Cardioscope BP+ works**

The Cardioscope BP+ measures both central and peripheral blood pressure as well as arterial stiffness which is measured by an Augmentation Index.

The measurement of central blood pressure has been steadily emerging as a superior measure of blood pressure because it has been shown to be a stronger correlate of cardiovascular disease. Similarly, arterial stiffness, which although it increases over time, is associated with poor cardiovascular health.

The device uses a cuff placed around the upper arm as the primary means for occluding the radial artery. The novelty of the technol-

ogy is that the cuff is controlled so that certain suprasystolic blood pressure measures are taken as well as 'standard' systolic pressure, which is the pressure from the heart pumping, and diastolic pressure, which is the pressure from the heart resting between beats. The standard measures are taken first, then the cuff is inflated by about 30mg Hg (mercury), so that the suprasystolic reading can be taken.

What has been found is that when a blood pressure cuff is inflated above systolic pressure (to suprasystolic pressure) three distinct pulse waves can be plotted.

The first wave corresponds to the 'standard' systolic wave. The second wave is reflected from the distal abdominal aorta. These waves might also be described as early systolic and late systolic pressure waves. The third wave occurs at the beginning of the diastole, which is when the heart begins to fill with blood again.

Unlike other approaches to measuring arterial stiffness (in the form of an Augmentation Index), the Pulsecor approach is calculate an Augmentation Index as a ratio of late systolic pressure to early systolic pressure.

An alternative calculation of the Augmentation Index compares the difference between central systolic pressure and (central) inflection pressure and central systolic pressure and central diastolic pressure. The inflection pressure is measured at a particular point on the pulse wave where a slight change in the wave form occurs. The specific term for this point is the anacrotic notch.

### **The Market Opportunity**

The market opportunities for blood pressure management tools include hypertension, a condition which effects a quarter of the adult population, hypertension during pregnancy, congestive heart failure, sepsis and in specialist care settings such as intensive care, emergency and anaesthesia.

However, the accessing of these markets by companies with central blood pressure and augmentation index products (including Atcor Medical, Healthstats International, I.E.M GmbH, TensioMed, BP Labs and others) is problematic because of (a) the convenience, lower cost and wide dispersment of the traditional peripheral blood pressure cuff and (b) the fact that central blood pressure is still in an early stage of adoption (or acceptance) across the globe as a superior correlate of cardiovascular disease.

Some results from the longitudinal Strong Heart Study (in several thousand Native American Indians), which used the Atcor Medical device and was published in 2009, have been a key to identifying central blood pressure as superior to peripheral blood pressure, as a marker of cardiovascular disease. However, changing clinical practice can take decades despite the availability of new technologies, tools and data. It takes time because gathering the clinical and related economic data takes time.

The CardioScope BP+ is a potentially useful step forward in the world of blood pressure measurement because it is portable, is

**Bioshares Model Portfolio (21 June 2013)**

Company	Price (current)	Price added to portfolio	Date added
Atcor Medical	\$0.071	\$0.082	May 2013
Circadian Technologies	\$0.250	\$0.270	March 2013
Tissue Therapies	\$0.125	\$0.255	March 2013
Allied Healthcare	\$0.053	\$0.026	February 2013
Psivida	\$4.05	\$1.550	November 2012
Benitec	\$0.017	\$0.016	November 2012
Nanosonics	\$0.600	\$0.495	June 2012
QRxPharma	\$1.20	\$1.66	October 2011
Somnomed	\$0.90	\$0.94	January 2011
Cogstate	\$0.330	\$0.13	November 2007
Clinuvel Pharmaceuticals	\$1.85	\$6.60	September 2007
Universal Biosensors	\$0.65	\$1.23	June 2007

**Portfolio Changes – 21 June 2013****IN:**

No changes

**OUT:**

No changes

– *Uscom cont'd*

easy to use, delivers results in less than a minute, and provides feedback in an easy to understand numeric format as well showing pulse wave charts which can track arrhythmias. Additional software can also present an even greater array of data.

The prominence of feedback features, as a design factor, have potential benefits in the general practice, pharmacy and exercise settings where subjects can comprehend their cardiovascular health from several simple accurate numeric readings and adjust diet, lifestyle and exercise programs accordingly as advised.

**Competitive Landscape**

However, Uscom's CardioScope BP+ is not the only product that measures central blood pressure and calculates an Augmentation Index. Some companies' products may compete directly, such as TensioMed's Ateriograph (although not FDA approved) and BP Labs' Vasotens (also not FDA approved), whereas others, such as Atcor Medical's Sphygmocor may address different market sub-sectors, for example, the research and drug trials market.

**Next Steps**

The task ahead for Uscom is to integrate the new business and find savings across both businesses and complete distribution and licensing negotiations. Uscom may also explore the option of direct sales of the Cardioscope BP+ using a web-based sales platform.

**Commentary**

Uscom's acquisition of Pulsecor is satisfying from several points of view. The most important of these is that the technologies of both companies are not merely complementary but are rather synergistic, combining central blood flow measurement with central blood pressure measurement. Hence, new products that combine these two measurements could well emerge and open up new sales opportunities for Uscom.

From a business model perspective, Uscom now controls products with quite different price and market dynamics. The cardiac outputs monitor is a large capital expenditure item (US\$30,000) with a slow sales cycle directed towards hospitals, and which is also not reimbursed. In contrast, the sales dynamics for the Car-

dioscope BP+ have the potential to positively alter the cash flow characteristics of Uscom's business, based on a shorter decision cycle for a US\$3,500 product by buyers who are based in clinics (doctor's surgeries) as well as in hospitals.

**Summary**

Uscom is on the cusp of a step-wise growth in its business. It has a standard challenge to bed down the Pulsecor acquisition and to initiate sales of the Cardioscope BP+. It will need to strengthen its sales and marketing capabilities in a logical manner and develop a considered strategy for competing in a large and price sensitive market in the US. However, its experience in selling the USCOM 1a blood flow monitor may stand it in good stead going forward.

Uscom is capitalised at \$13.6 million.

**Bioshares** recommendation: **Speculative Buy Class B**

**Bioshares**

**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. For both groups, the rating “Take Profits” means that investors may re-weight their holding by selling between 25%-75% of a stock.

**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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