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In this edition...
Universal Biosensors has made very good progress with its program to develop three POC coagulation test devices for its partner Siemens. While the revenues from strips used in Lifescan's One Touch Verio blood glucose monitor are beginning to build, the Siemens program is now adding more balance to UBI's 'partner risk' profile. Cogstate anticipates a new income stream to begin soon, as Merck Canada rolls out the Cognigram test. Cost cuts have helped Atcor Medical post a half yearly profit result. Atcor is slowly edging towards growing sales in the specialist clinical setting, with its improved Sphygmocor XCEL ready to better meet user needs. Allied Healthcare Group is expected to make significant progress in 2013 with its Cardiocel tissue patch product.
Companies Covered: ACG, AHZ, CGS, UBI, IMU

	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 - current)	-3.8%
Cumulative Gain	**235%**
Av. annual gain (11 yrs)	**17.8%**

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Bioshares

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Edition 492

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

Revenue up 100% at Universal Biosensors

In 2012, Universal Biosensors (UBI: $0.80) doubled its revenue to $29.6 million (UBI's financial year ends in December). Its net loss improved for the year, reducing from $14.7 million in 2011 to $9.1 million last year. R&D costs increased by almost $4 million for the year to $13.5 million, reflecting the increased development work with Siemens for a suite of point-of-care (POC) coagulation tests.

UBI received $5.1 million from Siemens last year, including two milestone payments totalling US$3 million and the balance being for variations to the original contract. The company should generate similar revenue from Siemens in 2013. The company has four remaining milestones with Siemens, of which we expect two to be met this year.

In September 2011, UBI entered into a partnership with Siemens Healthcare Diagnostics to develop three blood diagnostic products in the coagulation market. The first product is a PT/INR test to be used to help calibrate correct warfarin dosage. Siemens has already given UBI a planned launch date for this product in 2013, which has not been publicly disclosed. It will be a mark of excellent progress to have brought the product to market two years after the partnership was established.

Points of feasibility for the second and third products were reached in mid 2012. From there, we expect the two tests would require two more years of development. According to this timeline, we would expect the second and third coagulation diagnostic tests to come onto the market in 2014.

Siemens – A Good Fit

The fit with Siemens is complementary. Siemens has a large presence in central laboratory testing, but does not have any coagulation testing products for use at the point of care. The readers for the professional PT/INR tests are likely to be considerably more expensive than the patient glucose meters that Lifescan sells (for which UBI manufactures the test strips). The market leader, CoaguChek from Roche, sells for around $1,000. Some sites have dozens of these readers. Roche currently has over 65% share of the point of care PT-INR market.

UBI will be the exclusive manufacturer of the test strips for Siemens. At a certain point, Siemens can elect to manufacture the strips itself, but it will have to reimburse UBI with a payment for each strip sold.

The UBI-Siemens products will compete against the incumbent products based on features and added benefits of the new test products. Siemens will market the tests to professional users through hospital buyers, specialty clinics and also probably to general practitioners at some levels.

The coagulation products combined have the potential to be as valuable as the glucose market for UBI. Use of UBI's PT/INR test for home use by patients has not been partnered with Siemens.

Cont'd over

Test Strips for Lifescan's One Touch Verio Blood Glucose Monitors

Lifescan is selling blood glucose test strips developed by UBI. The strips are used in a new device called the OneTouch Verio. The strips are made by UBI, although Lifescan has set up its own manufacturing facility in Scotland as well. In 2012, Lifescan sold around 220 million of the UBI-designed strips. This represents about 5% of the total glucose strips that Lifescan sells.

The advantages of the OneTouch Verio strips include an ability to contribute to pattern recognition, a feature which no competing products offer, as well as a high level of accuracy and reliability.

Valuation Challenge

The other 95% of the strips sold are used in the older OneTouch Ultra meters. UBI receives US 1 cent for each of its strips that are sold, regardless of who manufactures the strips. If the UBI strips were to completely replace the OneTouch Ultra strips, then this could represent an annual royalty stream to UBI of around US$45 million a year. However, there are many millions of users of the Ultra system, and they will need to be changed over to the Verio meter. Numbers will also increase from new diabetics adopting the Verio system. At some point, Lifescan has the option to buy out this royalty obligation for an undisclosed sum. That this sum is confidential makes it difficult to accurately value the company.

UBI CEO Paul Wright believes that Lifescan is clearly committed to the Verio test strip platform. This OneTouch Verio platform continues to be publicly highlighted by Lifescan (Johnson &Johnson). 'They have spent a lot of money on this product,' said Wright. The glucose test strip side of the business is now profitable for UBI, generating a gross profit margin in dollar terms of $6.1 million last year.

Capital Raising for R&D

Late last year UBI raised $13 million to fund its additional R&D. This includes the coagulation products, and the immunodiagnostics which the company says it is close to reaching proof-of-concept and is to be expected to occur this year. Proof-of-concept for molecular diagnostics, where DNA of pathogens can be detected on a strip, is further away.

R&D is expected to decrease once the coagulation products have been developed. The company's head count has remained stable, at around 100 people.

UBI is capitalised at $139 million.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

Cogstate Test to be Launched into GP Market in Canada

Cogstate (CGS: $0.37) will soon begin to receive income from its fourth business unit. The company's partner Merck will start generating sales of Cogstate's Cognigram test in Canada shortly. The Cognigram test will help general practitioners identify early signs of neurodegenerative disease, including early stage Alzheimer's disease.

To date, staff at eight centres have been trained. A further 15 are expected to be ready by the end of March with 150 expected to be active by the end of 2013, according to Cogstate CEO Brad O'Connor at its half-yearly results briefing. All of Merck's sales force has now been fully trained. To date 90 GPs have signed on to use the test. Doctors will recommend the test to patients, who will then go to a centre Merck currently uses to deliver other therapies.

At the moment 94% of the company's revenue is generated in the clinical trials business. Use of the company's products for concussion management in sport generated just under $140,000 in revenue. Cogstate's cognitive sports training products generated sales of $132,000. The sports products revenue in total increased by just under $200,000 for the six months over the previous corresponding period.

Cogstate will concentrate on securing the product's entry into the Canadian GP market for neurodegenerative diseases. It will need to see adoption of the product occurring in Canada before it looks to license the product for additional regions. Sales of the test will be recorded by Cogstate, with Merck receiving a fee for their sales and marketing activities around the test. The company will provide further updates on the Cognigram product in coming weeks.

The commercialisation of this test represents excellent progress, following the formation of the collaboration with Merck in June 2012.

Core Business – Clinical Trials

For the half year, the company generated revenue of $6.1 million, with a net loss of $0.5 million. The clinical trials business is profitable, with just under $900,000 invested in the company's new product streams, being the sports and GP market. Investment into the new businesses is expected to be similar for the second half.

Sales for the full year are expected to exceed $11 million, with forward contracted revenue of $10.6 million, of which $4.75 million is expected to be recognised in this financial year. The company had $4.2 million in cash at the end of last year.

Drivers of the clinical trials business include a return to activity in drug testing for schizophrenia related drug programs (which dropped off two years ago), testing drugs to treat depression, and in paediatrics, where the FDA is increasingly wanting to see cognitive data. Alzheimer's disease only represents a small market for Cogstate at the moment, but is expected to be a big driver in later years. Two weeks ago the FDA released guidance on early stage

Cont'd over

Atcor Posts First Half Profit of $2.3 Million

Atcor Medical (ACG: 9.9 cents) posted a welcome half year result. Sales increased by 43% to $5.4 million, its second largest ever half year of sales. More importantly, the company delivered a net profit for the half of $2.27 million.

US Pharma the Main Driver

This result was assisted by an R&D tax rebate of $700,000. The main driver of sales was a strong increase in orders from pharmaceutical companies which use the company's central blood pressure measurement test in clinical trials. The company had secured some large sales orders in the half from its pharmaceutical customers, and its central blood pressure test is being expanded for use in other disease areas, including cardiovascular toxicology associated with oncology drugs and in diabetes.

Four large pharmaceutical companies have returned to use the Atcor test, and it is also getting sales from biopharmaceutical companies.

The company's net result was improved by a reduction in costs implemented last year, when about $1 million of annual costs were eliminated. For the company to be sustainable and profitable, sales need to be above $9 million a year. The company should be profitable for the full year, given the strong first half result.

In Australia and New Zealand use of the product in the clinic by GPs and specialists increased 20%. This was helped by the introduction of an improved version of the test, called the Sphygmocor XCEL. This test is much easier to use, where a cuff is placed around the arm. The original product requires the health practitioner to locate the pulse with a small sensor.

Sales in Europe were steady, in Asia sales declined, and in the US clinical market sales (used by doctors) also declined. US clinical sales will be assisted this year with the new device which was released in November last year, and in January this year the company received a Category III reimbursement code for the US market.

Atcor is capitalised at $15 million. It had cash of $2.1 million at the end of last year.

Bioshares recommendation: **Speculative Hold Class B**

Bioshares

– *Cogstate cont'd*

disease intervention in Alzheimer's, which O'Connor said will open the door for more sensitive tests like the one from Cogstate.

Sports Testing – Axon Sports

Cogstate's subsidiary, Axon Sports, is currently selling sports training products in the gridiron and baseball markets in the US. These products are distinctly different to the company's cognitive testing platform. These products help train the athlete's brain, using repeated visualisations of rapid action sports sequences.

The company is developing two products at this stage. The focus is initially on authenticating the products with elite sports people. The company will market these products via i-Phone and i-Pad apps, and Android apps. In the next six months the company will look to release a sports training product for soccer. It will start to market the products more actively in the next three months, once the apps have been finalised. The company will seek to find partners to assist with marketing the products, and does not expect to be investing large amounts itself to market the products.

Cogstate is capitalised at $29 million.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

The Year Ahead for Allied Health

Allied Healthcare Group (AHZ: $0.026) has set itself four objectives for 2013. The first is to grow revenues from its operational business; the second is gain EU approval (CE Mark) for Cardiocel, the company's tissue implanted patch product. A third goal is to submit a registration dossier for Cardiocel to the FDA, using the 510k pathway. A fourth objective is for Allied's investee company, Coridon, to commence a Phase I trial of its HSV vaccine.

These goals sit within CEO Lee Rodne's ambition to build a global healthcare business.

Recent Capital Raisings – $4.6 M

Allied completed a $1.7 million placement in December 2012. This was followed by a share purchase plan which raised $2.9 million. These two funding rounds totalled $4.6 million. Allied retained cash of $2 million at December 31, 2012.

The company posted a half-year loss of $2.2 million. Revenues for the half year were $3.7 million, compared to $3.3 million for the same period a year ago

Cardiocel Update

Cardiocel is a tissue patch product that is used to repair heart defects. Its initial application is for the treatment of heart defects in children who have been diagnosed with congenital heart disease.

Cardiocel is a tissue product sourced from bovine pericardium that has been treated with Allied's ADAPT processing technology. This process, invented at the University of Western Australia, strips the source tissue of cells, RNA and DNA, to leave a collagen scaffold that can be populated with a patient's own cells.

The principle advantage of the ADAPT process is that it is not as harsh as other methods, which use formaldehyde, and which means the ADAPT treated tissue is less prone to calcification or hardening.

A Phase II study of Cardiocel in children showed no evidence of calcification at six months or 12 months post implant. Furthermore, at three years post implant, calcification has not appeared in the transplanted tissue. This longer term data is expected to be published this year. With other tissue treatment approaches, evidence of calcification can be expected to appear within 3-6 months.

Cardiocel may win support from heart surgeons not only because it is less likely to be subject to calcification but also because of its handling characteristics and ease of ease. According to Allied, surgeons can cut and manipulate sheets of Cardiocel with relative ease.

The product is currently working its way through the CE mark approval process. Allied has now gained ISO13485 certification, which recognises the implementation of a quality management system. Approval is expected in 3-4 months time.

Clinical Relevance

Early evidence of the clinical relevance of Cardiocel exists through its uptake at the Mater Hospital in Brisbane, where more than a dozen patients have received the product under an Authorised Prescriber scheme. Similar access is desired by a surgeon at the Royal Children's Hospital in Melbourne.

Pricing and Marketing of Cardiocel

At this stage, Allied plans to market Cardiocel directly for the treatment of congenital heart defects. The global target market is 150 key centres with 30 major centres in Europe. Allied currently has the capacity to supply 3000 units a year.

Allied is currently assuming a target price for Cardiocel of around $1,000 per unit. Its goal, however, from a price perspective is to build market share and build the price upwards as the product becomes accepted.

Other applications of ADAPT treated tissue include tissue used in heart valves, in hernia and pelvic floor repair.

Cardiocel has the potential to be used in heart valve repair because the label being sort by Allied covers the use of Cardiocel for intra-cardiac repair. However, the company plans to conduct a study in 20-30 patients to evaluate Cardiocel in heart valve repair so that the product can be specified for heart valve repair, presumably both mitral and aortic valves.

Coridon and HSV-2 Update

Allied holds 48% of Brisbane-based vaccine company Coridon. Coridon is commercialising a DNA vaccine technology which activates both a cellular (T-cell) response and an antibody response. To date, Allied has invested $5 million in Coridon.

Herpes Simplex Virus 2 (HSV2) POC Study

Coridon will begin a 20 patient Phase I trial in healthy subjects, who are HSV2 -negative. Although the Phase I study is primarily a safety study, the study is expected to generate data pertaining to the vaccine's immunological power.

Summary

Allied Medical has made substantial progress with Cardiocel. Evidence has emerged that the product is both desired and liked by heart surgeons. The prospects of sales of Cardiocel beginning this year will add credibility to CEO Lee Rodne's claim of making Allied a global business. The support of a committed executive team is also another sign that Allied is on the way to creating significant value for investors. The stock has been added to the Bioshares Model Portfolio.

Allied Healthcare Group is capitalised at $27 million.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

Bioshares Model Portfolio (22 February 2013)

Company	Price (current)	Price added to portfolio	Date added
Allied Healthcare	$0.026	$0.026	February 2013
Psivida	$1.82	$1.550	November 2012
Benitec	$0.013	$0.016	November 2012
Nanosonics	$0.470	$0.495	June 2012
Osprey Medical	$0.50	$0.40	April 2012
QRxPharma	$0.99	$1.66	October 2011
Somnomed	$1.05	$0.94	January 2011
Cogstate	$0.380	$0.13	November 2007
Clinuvel Pharmaceuticals	$2.35	$6.60	September 2007
Universal Biosensors	$0.80	$1.23	June 2007

Portfolio Changes – 22 February 2013

IN:
Allied Healthcare has been added in recognition of key milestones ahead in 2013.

OUT:
Alchemia has been removed due to uncertainty pervading the company's strategy for completion and funding of its clinical program and uncertainty regarding the overall direction of the company.

Imugene – What to Look Out For

In 2012, Imugene (IMU: 0.9 cents) absorbed the Linguet drug delivery assets of Consegna Group. It discontinued work on the company's founding asset, a vaccine technology that had been in development in to treat pig and chickens. (Clearly, the company's name is now out of date and we expect it to be changed in due course.)

Imugene is now led by Dr Nick Ede (CEO), who is based in Melbourne. His biotech industry experience includes stints at Chiron, Mimotopes, Eqitx and Adistem.

The chairman of the Imugene board is Steve Harris, a UK-based pharmaceutical industry executive who has had roles with ICI Pharmaceuticals, Merck, Eli Lilly, Boots and Reckitt and Colman, (now Reckitt Benckiser). The third board member is Paul Hopper, who also serves as chair of Viralytics.

The Linguet Technology

Imugene is now focused on developing generic drugs that can be improved by delivery through the vein-rich areas in the cheek of the mouth or under the tongue.

Drugs that can delivered through this route of administration may have the advantage of a rapid uptake, may be administered without the pain of injection and also avoid the problems that oral drugs face when the pass through the gut and the liver. Lower dose forms are also another potential advantage.

Strategy Pending

Imugene is currently formalising its business strategy with the expectation that it will have this in place by March.

That strategy is expected to be more explicit about the generic drug candidates it intends to develop and to have developed greater certainty about development pathways and market opportunities.

One potential candidate drug candidate flagged by the company is a metabolite of Vitamin D (cholcalciferol) product. Vitamin D represents a potential market opportunity because of Vitamin D deficiency.

Vitamin D is formed through the exposure of skin to sun. However, Vitamin D deficiency has possibly increased as a health issue because of public health campaigns to decrease people's exposure to sun. A much more sedentary, indoors lifestyle could also be a contributing factor. Sedentary elderly people could also be prone to Vitamin D deficiency.

A commercial opportunity may exist to develop a drug that is less likely to contribute to problems of overdosing of Vitamin D.

As a 'test candidate' Imugene envisages that it could take between 18 months and two years to get its Vitamin D analogue to the market, for less than $500,000. The low cost is a function of the need to do only the most basic pharmacokinetic equivalence studies.

An external validation for the Vitamin D opportunity was the recent acquisition in January 2013 of Phase III-stage Cytochroma by OPKA Health for US$100 million in shares. Cytochroma is developing a Vitamin D prohormone for secondary hyperparathyroidism (SHPT) in patients with stage 3 or 4 chronic kidney disease (CKD) and Vitamin D insufficiency. SHTP occurs as a consequence of Vitamin D deficiency. Between 70% and 90% of CKD patients have Vitamin D deficiency. Cytochroma's drugs come in injected and oral forms.

Outsourcing Model

Imugene's business model relies on the use of consultants, drug formulators and manufacturers, including certain advisory services from the chairman's pharmaceutical consultancy firm. Expertise provided by Harris is a potential positive. A potential weakness is that the relationship may, through its fee-for-service and retainer structure, not include sufficient incentives to complete the drive to successful commercial outcomes.

Summary

Imugene is still transforming itself into a new business and requires further time to finalise and validate its plans.

Imugene is capitalised at $3 million and retained $0.68 million in funds at the December 31, 2012.

Bioshares recommendation: **Under Review, Pending IMU's Formalisation of Development Plans**

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

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