

In this edition...

Universal Biosensors' partner Lifescan has, after many months of waiting and several product iterations, launched the blood glucose monitor, the OneTouch Verio, in the US market. UBI is hopeful Lifescan will transition all users of its glucose meters to the OneTouch Verio product. Lifescan has one-third of the self-monitoring glucose market in the US, and about 20% in Europe. Prima Biomed has commenced its 800 patient Phase III trial for CVac, an immunotherapy for treating ovarian cancer, with recruitment expected to be completed in 2013 H2.

The Editors

Companies Covered: UBI, PRR, Survival Index

	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 - May '10)	49.2%
Year 10 (May '10 - May '11)	45.4%
Year 11 now commenced	-24.3%
Cumulative Gain	219%
Av. annual gain (10 yrs)	21.2%

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Bioshares

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

Universal Biosensors – OneTouch Verio Launched in US; Sales Expected to Accelerate

Universal Biosensors' (UBI: \$0.77) partner **Lifescan** has launched the companies' new glucose monitoring system in the US, called the OneTouch Verio. The product took some time to gain approval in the US but is now available in all major world markets.

UBI manufactures the test strips for the Verio systems in Melbourne. It receives a manufacturing fee and around a one cent per strip service fee from each strip sold, regardless of who makes the strips. This service fee alone could eventually see the company receive \$40 million a year, once a complete transition is made.

To make that transition, users need to be moved across to a new diagnostic meter, which sells for US\$70. The new meter has several advantages for users. The OneTouch Verio is the only meter to proactively alert users when their blood glucose pattern changes compared to previous trends, according to Lifescan.

The UBI design allows only a 'speck of blood' to be used, scans each sample 500 times to correct for interferences, providing results in five seconds.

The new system also has a significant advantage for Lifescan, that being the cost involved in making the strip using the novel and patented UBI design is much lower, at equally manufactured quantities. This will not have an effect on the price of the strips in the US, with the strips reimbursed by Medicare in the US and health insurers, as are the meters.

UBI has now moved out of the transition manufacturing phase, which means volumes have increased. Revenue to UBI should start to accelerate from here as the volumes move into the vertical phase of the S-curve. UBI receives its orders one month in advance, with guidance given for four and 12 months ahead.

CEO of UBI, Paul Wright, is hopeful Lifescan will eventually transition all of its glucose meters to the Verio system. Lifescan's existing glucose testing platform, the OneTouch Ultra systems, is now 10 years old.

The current meter launched in the US is the third generation developed by Lifescan, called version 2.5. This will likely replace version 2.0 that is being currently used in Europe and may help improve product take-up and market share for Lifescan in the glucose testing market.

Lifescan has 33% of the US self-monitoring glucose market, which is expected to grow from US\$3.8 billion in 2010 to US\$5.6 billion in 2015. The US is where Lifescan has the greatest market share and is arguably the most important market to Lifescan. In Europe, Lifescan has only around a 20% market share of the self-monitoring glucose market.

– UBI cont'd

Last year UBI assisted Lifescan in building a second plant in Scotland that Lifescan will operate, to manufacture the Verio glucose test strips. We expect both sites will be used to make the test strips.

PT/INR Test

Last year UBI partnered its second program with **Siemens Healthcare Diagnostics**, for the development of a point-of-care use prothrombin time test (PT/INR) which is used to calibrate warfarin dosage. The development is progressing well. It was previously anticipated the product would be filed for approval by March this year. However modifications to the design output of the system means the test will more likely be ready to submit for approval towards the end of this year and we estimate should be on the market in 2013.

This product is a major step up in the value chain for UBI. UBI has independently advanced the product further prior to partnering with Siemens, compared to the glucose test strips it makes for Lifescan. The reimbursement price per strip for PT/INR tests is also up to 10 times higher than for glucose strips. This means UBI could possibly receive between 50 cents and \$1.50 per strip it makes although the breakdown of its commercial arrangement with Siemens has not been revealed.

Immunoassays

UBI is progressing its immunoassay tests, the first product likely to be a coagulation test using the D-dimer antibody. Incorporating the company's diagnostic meter with antibody tests is a major step-up technically. If successful it can open up a whole new

range of antibody-based tests to the UBI platform. UBI is also working on a CRP immunoassay, a common test for measuring inflammation in the body.

The rationale for developing a D-dimer test (with many already available) is that an improved test could offer advantages over existing tests and potentially even expand the market. The D-dimer test is used often in an emergency setting to rule out a pulmonary embolism from patients with severe chest pain. Existing tests require manual handling of reaction chemicals and are not definitive.

Other Programs

UBI is working on another (undisclosed) glucose testing product with Lifescan. It has also recently in-licensed technologies for Australian company SpeedDX to investigate applying the UBI platform for building DNA and RNA tests. This potentially would allow detection and identification of viruses and bacteria in minutes, rather than sending samples off to pathology labs for complex testing.

UBI is capitalised at \$122 million. It had \$15 million in cash at the end of last year.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

Prima Biomed Starts Phase III Ovarian Cancer Vaccine Trial

Prima Biomed has recruited the first patient into its Phase III study for its ovarian cancer study with CVac, a dendritic cell immunotherapy. The study will recruit 800 women across 22 countries in 150 centres.

Over 30 clinicians have been trained for delivery of the therapy in the US, with the first patient being from the US. This week the company co-ordinated a physician training program in Prague, where around 90 clinicians attended. It's expected that around 70% of the patients will be recruited from Germany.

According to CEO Martin Rogers, one of the reasons physicians are very interested in this therapy is because there are no other treatment options for patients after chemotherapy. With CVac, there is minimal downside, with none of the toxicity issues associated with chemotherapy. Arguably it is a therapy that certainly deserves to be investigated.

Prima is now well positioned to complete the current trial and to get an answer on the effectiveness of the therapy. The program is funded from its existing funds to early 2014, the end of recruitment. In May last year the company raised \$41.4 million at 28 cents a share.

The company expects to complete recruitment in the trial in the

second half of 2013. The first interim look at results from the Phase III study will occur once recruitment is complete, with final results out at the end of 2014.

In this Phase III trial, Prima will also look at the responders in the trial, and will use immunodiagnostic tests to understand why the patients are responding. This will provide very useful additional information.

Another benefit for Prima is that CVac is unlikely to be open to generic competition once its patents expire due to the nature of the therapy. Competitors will likely be required to conduct their own clinical studies should they wish to develop a similar cancer vaccine.

Results from Phase IIb Study

In September last year the company completed recruitment in its Phase IIb study, which has recruited 63 patients who had received first or first and second line chemotherapy treatment. Interim safety results are expected to be released June this year at ASCO, with final results to be released at the end of this year.

One thing to note with the current Phase III CANVAS study is that that study will only recruit women in remission after first line treat-

Cont'd on page 5

4.7B Reporting Companies – Cash Balances December 31, 2011 Sorted by Survival Index

Code	Company	Cash Receipts (\$M)	Nett Op. Cash Fl. (\$M)	Cash End 31/12/11 (\$M)	Survival Index	Comments/Events post reporting date		
1	LBT	LBT Innovations	\$0.0	\$0.1	\$3.4	A	Not App	
2	HCT	Holista Colltech	\$2.6	\$0.1	\$1.2	A	Not App	
3	PCC	Probiomics	\$0.4	\$0.0	\$0.3	A	Not App	
4	QRX	QRxPharma	\$0.0	-\$1.9	\$32.9	A	8.6	
5	NDL	NeuroDiscovery	\$0.0	-\$0.2	\$2.6	A	7.1	
6	SPL	Starpharma	\$1.2	-\$3.9	\$49.0	A	6.2	
7	AVX	Avexa	\$0.0	-\$1.2	\$14.4	A	5.8	
8	BIT	Biotron	\$0.0	-\$1.0	\$9.1	A	4.5	
9	BRC	Brain Resource Corp	\$0.5	-\$1.6	\$13.6	A	4.1	
10	BNO	Bionomics	\$1.8	-\$2.3	\$17.9	A	3.9	
11	MSB	Mesoblast	\$0.1	-\$31.7	\$240.5	A	3.8	
12	RVA	Reva Medical	\$0.0	-\$16.2	\$58.1	CY	3.6	
13	RHT	Resonance Health	\$0.8	-\$0.2	\$1.3	A	3.3	
14	AVH	Avita Medical	\$1.6	-\$1.7	\$10.8	A	3.2	
15	GID	GI Dynamics	\$0.2	-\$23.4	\$65.0	CY	2.8	
16	PXS	Pharmaxis	\$0.9	-\$19.1	\$101.2	A	2.7	
17	PRR	Prima Biomed	\$0.0	-\$9.7	\$47.5	A	2.5	
18	NEU	Neuren Pharmaceuticals	\$0.0	-\$3.1	\$7.5	CY	2.4	
19	OBJ	Objen	\$0.0	-\$0.8	\$4.0	A	2.4	
20	VL	Viralytics	\$0.0	-\$1.7	\$8.0	A	2.3	
21	ACL	Alchemia	\$0.0	-\$4.7	\$21.4	A	2.3	
22	SOM	Somnomed	\$6.4	-\$0.7	\$3.3	A	2.3	
23	ADO	Anteo Diagnostics	\$0.1	-\$1.3	\$5.5	A	2.2	
24	UBI	Universal Biosensors	\$17.8	-\$7.2	\$15.1	CY	2.1	
25	ACU	Acuvax	\$0.0	-\$0.3	\$1.0	A	1.9	
26	MGZ	Medigard	\$0.0	-\$0.1	\$0.5	A	1.8	
27	GTG	Genetic Technologies	\$3.8	-\$3.5	\$12.6	A	1.8	
28	MLA	Medical Australia	\$4.8	-\$0.3	\$1.2	A	1.7	
29	IMU	Imugene	\$0.0	-\$0.5	\$1.5	A	1.7	
30	NAN	Nanosonics	\$4.9	-\$2.8	\$9.2	A	1.6	
31	ACG	Atcor Medical	\$4.1	-\$0.4	\$1.1	A	1.5	
32	BLT	Benitec	\$0.2	-\$1.7	\$4.6	A	1.4	
33	BDM	Biodiem	\$0.6	-\$0.8	\$1.8	A	1.2	
34	UNS	Unilife	\$1.5	-\$18.5	\$41.1	A	1.1	
35	TIS	Tissue Therapies	\$0.1	-\$4.9	\$10.5	A	1.1	
36	EMS	Eastland Medical Systems	\$1.8	-\$1.1	\$2.2	A	1.1	
37	GBI	Genera Biosystems	\$0.0	-\$0.8	\$1.6	A	1.0	
38	CUV	Clinuvel Pharmaceuticals	\$0.8	-\$5.7	\$11.8	A	1.0	
39	ALT	Analytica	\$0.0	-\$0.5	\$1.1	A	1.0	
40	IPD	Impedimed	\$1.5	-\$6.2	\$12.1	A	1.0	
41	PBT	Prana Biotechnology	\$0.0	-\$3.9	\$6.7	A	0.9	Completed placement of ~\$0.8 M
42	CBB	Cordlife	\$3.4	-\$2.4	\$4.0	A	0.8	
43	PAB	Patrys	\$0.1	-\$2.7	\$4.2	A	0.8	Received \$2.3 M from \$3.4M Dec. capital raising
44	UCM	USCOM	\$0.4	-\$0.9	\$1.2	A	0.7	
45	ISN	Isona	\$0.0	-\$2.7	\$3.5	A	0.7	
46	OMI	Occup. & Medical Innov.	\$0.0	-\$0.2	\$0.2	A	0.6	
47	LCT	Living Cell Technologies	\$1.3	-\$2.1	\$2.5	A	0.6	
48	PYC	Phylogica	\$0.0	-\$3.3	\$3.9	A	0.6	To receive US\$1.35 M revenue in March quarter
49	ANP	Antisense Therap.	\$0.0	-\$1.3	\$1.5	A	0.6	
50	LER	Leaf Energy	\$0.1	-\$0.4	\$0.4	A	0.5	Announced right issue to raise ~\$1.4 M
51	BCT	Bluechiip	\$0.0	-\$0.5	\$0.5	A	0.5	Raised \$0.47 M from private placement
52	CBZ	Cbio	\$0.1	-\$7.6	\$7.3	A	0.5	Completed strategic review;undertaking scientific review
53	SIE	Scigen	\$14.8	-\$4.2	\$2.0	CY	0.5	Signed MOU with Actavis Group
54	CXD	CathRx	\$0.0	-\$3.7	\$3.3	A	0.4	Strategic change announced- now a catheter design business
55	SHC	Sunshine Heart	\$0.0	-\$7.2	\$6.4	A	0.4	
56	AYX	Austofix	\$0.7	-\$0.2	\$0.2	A	0.4	Has access to \$0.8 M bank facility; \$0.1 M drawn down
57	IMI	IM Medical	\$0.0	-\$1.7	\$1.2	A	0.4	Seeking to sell radiology business
58	AGX	Agenix	\$0.0	-\$1.1	\$0.7	A	0.3	
59	CGP	Consegna Group	\$0.0	-\$1.5	\$0.9	A	0.3	Completed placement of \$1.5 M
60	CDY	Cellmid	\$0.1	-\$1.4	\$0.6	A	0.2	Received tax refund of \$0.7 M
61	TDX	Tyrian Diagnostics	\$0.3	-\$2.2	\$1.0	A	0.2	Company winding down activities
62	AHZ	Allied Healthcare Group	\$3.2	-\$1.9	\$0.6	A	0.2	
63	ACW	Actinogen	\$0.0	-\$0.7	\$0.2	A	0.2	
64	SLA	Solagran	\$0.6	-\$2.9	\$0.4	A	0.1	Added \$1.1 M in debt facilities
65	HTX	Healthlinx	\$0.0	-\$1.3	\$0.1	A	0.0	Has access to \$3M funding agreement with US investor
66	BNE	Bone Medical	\$0.0	-\$0.5	\$0.01	A	0.0	US\$6 M Convertible note facility with La Jolla Cove Invest. Part.

Bioshares Model Portfolio (3 February 2012)			
Company	Price (current)	Price added to portfolio	Date added
QRxPharma	\$1.56	\$1.66	October 2011
Mayne Pharma Group	\$0.350	\$0.435	September 2011
Genetic Technologies	\$0.13	\$0.18	August 2011
Acrux	\$3.61	\$3.37	June 2011
Bioniche	\$0.72	\$1.35	March 2011
Somnomed	\$0.97	\$0.94	January 2011
Phylogica	\$0.039	\$0.053	September 2010
Biota Holdings	\$0.81	\$1.09	May 2010
Tissue Therapies	\$0.34	\$0.21	January 2010
Atcor Medical	\$0.09	\$0.10	October 2008
Impedimed	\$0.56	\$0.70	August 2008
Bionomics	\$0.41	\$0.42	December 2007
Cogstate	\$0.27	\$0.13	November 2007
Sirtex Medical	\$4.85	\$3.90	October 2007
Clinuvel Pharmaceuticals	\$2.20	\$6.60	September 2007
Pharmaxis	\$1.01	\$3.15	August 2007
Universal Biosensors	\$0.77	\$1.23	June 2007
Alchemia	\$0.330	\$0.67	May 2004

Portfolio Changes – 3 February 2011

IN:
No changes

OUT:
No Changes

4.7B Reporting Companies – Cash Balances December 31, 2011 (Cont'd)

Legend:

Not App. : The SI calculation for these companies is not calculated due to the companies reporting positive operational cash flows, or in some cases marginally negative operational cash flows.

A: The SI calculation for these companies is based on the last two quarters NOCF.

CY: The SI calculation for these companies is calculated on the last four quarters of NOCF.

Commentary

At December 31, 2011, from a reporting pool of 66 companies, we calculated 26 companies to have a Survival Index of less than. Post the December 31, five companies completed placements, announced right issues or received tax refunds. Tyrian Diagnostics is in a wind down phase, while CBio is completing a scientific review following the failure of its Phase II trial of its Xtoll product for rheumatoid arthritis in 2011. Debt funding remains a source of funds for at least four companies.

At the cash rich end of the spectrum, significant funds are held by Mesoblast (\$240.5 million), Pharmaxis (\$101.5 million), GI Dynamics, (\$65 million), Reva Medical (\$58.1 million), Starpharma (\$49 M), Prima Biomed (\$47.5 million), Unilife (\$41.1 million), QRxPharma (\$32.9 million) and Alchemia (\$21.4 million). These nine companies hold, in aggregate, \$657 million in cash.

Each quarter, the majority of ASX listed biotech companies are required to report their cash positions. In turn, a key analytical measure we present each quarter is the 'Survival Index' (SI). The index measures how many years those cash reserves will last, based on a company's recent spending patterns. It is limited because it does not account for companies that may increase spending in the next period of activity.

The index is derived for this quarter by dividing the average of net operational cash flows (NOCF) for the last two quarters ending December 31, 2011, into each company's cash assets as recorded at December 30, 2011. For companies that report on December 31 full year basis, the index is based the full years worth of net operational cash flows (NOCF). The NOCF is the net of receipts and outgoings incurred in support of operational activities.

As a rule of thumb, companies that present with an SI of less than one are likely to be raising funds to support their activities, or are in the process of doing so. A healthy SI is either two or more. Companies with SIs of less than 0.5 may be in positions of funding stress and investors should investigate such stocks with a greater degree of concern.

Small cap life science companies that are not required to comply with the 4.7B Rule include: Acrux, Advanced Medical Design and Manufact., Immuron, Biota Holdings, Bioniche, Cogstate, Circadian Technologies, Clovercorp, Compumedics, Cryosite, Cyclopharm, Teleso Technologies, Ellex Medical Lasers, IDT Australia, ITL Corp, Calzada, Medical Developments Int., Novogen, Optiscan Imaging, Progen Pharm., Phosphagenics, Sirtex Medical and Virax Holdings.

Re-domiciled companies, pSivida and Heartware International no longer comply with the 4B Rule.

– PRR from page 2

ment. There will be a better opportunity to gauge the effectiveness of CVac in the Phase III study because of the earlier disease status of patients, compared to the later disease status of the patients enrolled in the Phase IIb study.

Dendreon Slumps

Prima Biomed has benefited from the interest and success of the leader in the cancer vaccine space, Dendreon. On the flip side, negative sentiment or commercial setbacks at Dendreon also likely impact Prima's share price. Dendreon's share price has fallen 68% from its 12 month high although it is still capitalised at \$2.1 billion. The reason for the fall is that it has lowered its sales projections in the last year.

Dendreon's Provenge was approved in April 2010 by the FDA. Sales forecasts for 2011 were between US\$350-US\$400 million. However the company ended up generating sales of around US\$230 million for the year. Those sales are now starting to pick up, with Provenge sales of US\$82 million in the fourth quarter of 2011, up 24% over the September quarter last year.

Summary

Some strength should return to the Prima Biomed share price as Dendreon builds sales with Provenge, which is now occurring. Prima will look to fill the gap in its pipeline (Phase I and Phase II programs) as it progresses its pivotal study with CVac, which if successful, will enable the company to file the therapy for approval. The company is well positioned to commercialise CVac as well as leverage its expertise to acquire and develop other oncology programs.

Prima is capitalised at \$170 million with \$47.5 million in cash at the end of 2011.

Bioshares recommendation: **Speculative Buy Class B (Suits longer term investors)**

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

Corporate Subscribers: Pharmaxis, Starpharma Holdings, Cogstate, Bionomics, Circadian Technologies, Biota Holdings, Impedimed, QRxPharma, Patrys, LBT Innovations, Mesoblast, Atcor Medical, Tissue Therapies, Viralytics, Phosphagenics, Immuron, Phylogica, Bluechiip, pSivida, Antisense Therapeutics, Benitec BioPharma, Allied Healthcare Group, Genetic Technologies

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