

# Universal Biosensors Ltd

## FDA Approval and US Launch of Verio a growth driver

The approval and the imminent launch of an upgraded OneTouch Verio blood glucose meter in the North America market will be a defining event for UBI, as:

- It confirms LifeScan's commitment to the OneTouch Verio.
- The USA is the largest market for blood glucose testing, comprising over 40% of global sales and 50% of LifeScan's sales. LifeScan is also expected to use the new meter system to boost promotion of Verio in the recently launched European markets and to launch in additional markets.
- This will result in a significant boost to both product sales and service revenue, taking UBI to a cash flow positive and profitable position in CY2013.

## Siemens Partnership provides second growth path

UBI has announced a Collaboration Agreement with Siemens Healthcare Diagnostics for the development and commercialization of test strip and meter system for the point-of care coagulation testing market, based on:

- Development of a modified version of UBI's PT/INR test system, followed by other coagulation tests. UBI will manufacture and supply the test strips, while Siemens will register, market and sell each testing system globally.
- UBI will receive an initial US\$3m payment and 6 milestone payments, relating to feasibility, regulatory submissions and launch of products.

This is an important announcement for UBI, as:

- It gives UBI entry into the US\$750m coagulation testing market, which is expected to grow rapidly to a US\$1.3b in FY2020. This market is more profitable for UBI with margins likely to be over 40%.
- Siemens is a major global healthcare leader, especially in the blood clotting area, enabling the registration and marketing of the testing system globally. There is also potential for other tests in the blood coagulation area.
- It validates UBI's R&D and commercialisation program outside of diabetes.

## Developing a Molecular Diagnostic test path

UBI is moving into the US\$3.2b molecular diagnostics sector, with a non-exclusive licence for SpeedX's MNAzyme technology for DNA and RNA testing. This adds to UBI's growth opportunities and takes it into a high value, high growth area.

## Forecasts

Our forecasts for CY2011 and CY2012 for the OneTouch Verio are mostly unchanged, while the PT/INR forecasts have been adjusted to reflect milestone payments, some extra development costs and a later launch date.

The forecasts for CY2013 have been adjusted for a launch by Siemens in early CY2013 and the continued ramp up of Verio sales, with UBI moving to a cash flow surplus and profits in CY2013.

## Reasons to BUY

**Growth Markets** – Exposure to large rapid growth Point-of-Care Healthcare sectors, forecast to grow at around 12% pa.

**Industry Position** – Leading edge technology, a strong IP position, backed by a strong R&D team, strong partnerships and successful management and Board.

**Improving Financial Position** – With escalating revenue from LifeScan, substantial global market potential in the coagulation market and subsequent products, UBI is expected to be cash flow positive and profitable in FY2012.

**Balance Sheet Strength** – A strong Balance Sheet, with net cash of \$17.5m.

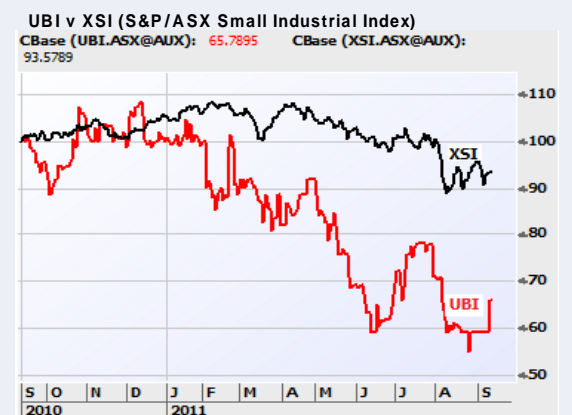
**Valuation** – Currently trading at a 50% discount to our valuation of \$2.02 ps.

## UBI.ASX BUY

22 September 2011

Price	\$1.00
Target price	\$2.02
Valuation method	DCF
GICS sector	Healthcare
12 Mth Price Range	\$0.84 - 1.65
Avg monthly t/o	2m
Market Capitalisation	\$159m
Shares on issue	159m
Enterprise value	\$136m
Previous rating	<b>BUY</b>

Year Ended Dec 30		09A	10A	11E	12E	13E	14E
Revenue	\$m	22	18	18.4	33.0	53.9	83.3
EBITDA	\$m	3.5	-4.8	-7.0	-1.6	8.4	21.8
EBITDA margin	%	495.7	32.4	37.6	39.8	42.2	47.0
EBIT	\$m	0.6	-7.8	-10.6	-5.3	4.4	17.6
EBIT margin	%	14.6	-42.9	-57.7	-16.2	8.2	21.1
NPAT	\$m	<b>1.4</b>	<b>-6.6</b>	<b>-9.8</b>	<b>-5.0</b>	<b>4.6</b>	<b>17.9</b>
EPS	cps	0.9	-4.2	-6.2	-3.2	2.9	11.2
DPS	cps	0.0	0.0	0.0	0.0	1.5	6.0
Franking	%	0.0	0.0	0.0	0.0	0.0	0.0
PER	x	na	na	na	na	34.2	8.9
Dividend yield	%	0.0	0.0	0.0	0.0	1.5	6.0
NTA/share	\$ ps	32.7	28.5	22.3	19.1	22.1	31.8
EV/EBITDA	x	36.1	-28.2	-20.2	-88.8	16.8	5.8
Gearing (D:E)	%	0.0	0.0	0.0	0.0	0.0	0.0
P/OCF	x	49.5	-37.3	-38.9	na	24.3	8.3
ROA	%	1.2	-14.5	-21.8	-12.0	9.5	29.9
ROE	%	2.9	-13.7	-24.3	-15.3	14.2	41.7
Interest cover	x	na	na	na	na	na	na



Source: IRESS

### Activities

Development & commercialisation of medical diagnostic devices, especially for point of care in vitro tests.

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## FDA Approval for an Upgraded Blood Glucose meter

**Rollout of upgraded meter to follow FDA approval**

As expected, LifeScan has received FDA approval for an upgraded OneTouch Verio test metering system, which includes changes to design and additional features, although the strips are unchanged. While LifeScan initially received approval in February for a prototype meter and strips, which were marketed in Australia and Europe, the imminent US launch and major European promotion will be with the new meter.

This is a defining event, as:

**Verio a key driver of market share growth for LifeScan**

- It demonstrates LifeScan's ongoing commitment to the Verio, especially as it has struggled to maintain market share against new models and entrants. The promotion of OneTouch Verio will be based on an advantage over competing products, being accurate, precise, and cost effective.

**US a key market for LifeScan**

- The North American market is the largest global market at around 45%, estimated by GlobalData<sup>1</sup> to grow at a CAGR rate of 11% from \$2.87b in 2008 to \$5.5b by 2015. As LifeScan holds around 33% of the North American market, entry will significantly boost strip sales and royalty revenue.

**A pickup in penetration levels expected in Europe**

- Approval of the new meter is also a pre-cursor for:
  - Increased promotional level in Europe, where the prototype Verio meter had been introduced with minimal marketing and promotion. This rollout covered the Netherlands (January 2010), Italy and France (January 2011), and Germany, the UK, Ireland, Spain and Portugal (April 2011), comprising 90% of the European Union market.
  - The entry into new markets. The fastest growth in diabetes is in Asia and Central and South America, with forecasts of growth of 15.2% and 13% respectively, target markets for LifeScan.

**Conversion of existing LifeScan users will be progressive over 5 years**

- The US launch and European relaunch will boost UBI's strip sales to LifeScan as well as royalties based on total strip sales.

- It further validates UBI's ability to commercialise a testing system and manufacture strips, adding confidence for the commercialisation of the Coagulation (PT/INR) meter system.

It is important to note that total penetration of LifeScan's US and other established markets could take around 4 to 5 years, as existing users prefer the new model or the existing meter expires. LifeScan's last model change to the "OneTouch Ultra" saw full replacement over 5 years, corresponding to an expected meter lifespan of 4 to 5 years. This changeover along with market growth saw an increase in strip sales from 1.6b to 4.1b.

As the successful launch of 'Verio' is essential for LifeScan to alleviate some recent loss of market share, we expect a significant marketing program, comprising:

**New entrants or users of competing products a target for LifeScan**

- Targeting newly diagnosed diabetics and health professionals on the basis of the advantages of 'Verio' over the competitors. This market is significant with the International Diabetes Federation (January 2011) estimating that the global prevalence of diabetes among adults aged 20-79 years will increase from 6.6% in 2010 to 7.8% by 2030, while Business Insights forecast growth in the blood glucose self-testing market of 5% pa, from US\$9.9b in 2010 to US\$13.3b in 2016. The latter is conservative, below Global Data's forecast growth of 10% pa.

- An ongoing information and promotion campaign to existing 'Ultra' users, on the basis of the advantage of the 'Verio' over the 'Ultra'.

- Targeting new markets, especially Asia and 3<sup>rd</sup> world markets, where the incidence of diabetes is increasing at a faster rate and the penetration of meters is lower.

- The offer of a discounted price or free meter to encourage take-up. This will involve a significant capital outlay by LifeScan.

<sup>1</sup> Source – GlobalData, Global Self Monitoring Glucose Market, Published Nov 2009

### Blood Glucose Revenue Base

UBI's revenue growth in the SMBG market emanates from 2 sources:

**UBI to receive 9¢ per strip sold to LifeScan**

**Product Sales** – UBI supplies strips to LifeScan on a non-exclusive basis. We estimate that on a full pricing basis, UBI receives around US9¢ per strip, with a cost base of around US7.5¢ per strip on delivery to LifeScan.

LifeScan is expected to mostly supply US strips from CY2012 from its new 750m pa strip facility in Scotland, leaving UBI to supply other countries from its current capacity of 750m strips pa (from 1 line). While UBI has potential capacity for 2 lines, we expect longer term growth to be supplied from additional LifeScan lines.

**UBI to receive 1¢ per strip sold by LifeScan**

**Service Revenue** – UBI receives around US1¢ per strip on all strips sold by LifeScan. We also expect new R&D programs for LifeScan to commence in the 2H FY2011.

While LifeScan has not given any indication of the timing of a launch, we would expect a US launch in either late Q4 CY2011 or early CY2012. While we expect a buildup of strips ahead of the launch in Q4 CY2011, royalty revenues will only be received following the launch, when strips are sold.

### Forecasts

The forecasts below are conservative in terms of take-up rate. We expect a similar changeover timeframe to the LifeScan's last model change of 5 years, due to economic conditions and a longer lifespan for existing meters, unless LifeScan offers incentives or forces conversion through ceasing manufacture of "Ultra" strips. Accordingly, we are using a take-up of 60% to 70% by 2015 and full take-up by 2017, although volumes will also be driven by continual market growth.

The model for Blood Glucose is largely unchanged, but conservative on penetration rates and with no assumption on annual growth:

**Table 1 Blood Glucose Market - Forecasts**

Country	Total Blood Glucose Market Size (US\$m)	Test Strip Market				Verio Strip Sales					Total Verio Sales				
		Test Strips <sup>1,2</sup>		LifeScan Market Share		Verio % of LifeScan Sales <sup>3</sup>									
		(US\$m)	m	%	m	CY 11	CY 12	CY 13	CY 14	CY 15	CY 11	CY 12	CY 13	CY 14	CY 15
Netherlands	80	68	124	10	12	100	100	100	100	100	12	12	12	12	12
Australia	80	68	170	3	4	100	100	100	100	100	4	4	4	4	4
Italy	500	425	773	25	193	10	20	35	45	60	19	39	68	87	116
France	475	404	734	25	184	12	20	35	45	60	22	37	64	83	110
Germany	950	808	1,468	25	367	12	20	35	45	60	44	73	128	165	220
UK	470	400	726	20	145	10	20	35	45	60	15	29	51	65	87
Spain	420	357	649	20	130	8	15	30	40	55	10	19	39	52	71
Portugal & Ireland	50	43	77	20	15	8	15	30	40	55	1	2	5	6	9
<b>Launched Markets</b>	<b>3,025</b>	<b>2,571</b>	<b>4,721</b>	<b>22</b>	<b>1,051</b>						127	216	371	475	630
USA <sup>4</sup>	4,000	3,400	6,182	40	2,473	3	10	30	50	70	62	247	742	1,236	1,731
Other Europe <sup>5</sup>	600	510	927	20	185		3	15	30	45	0	5	28	56	83
<b>Approved &amp; Launched</b>	<b>7,625</b>	<b>6,481</b>	<b>11,784</b>	<b>31</b>	<b>3,709</b>						189	468	1,141	1,767	2,444
Rest of World <sup>6</sup>	2,175	1,849	4,108	15	616			5	10	35	0	0	31	62	216
<b>Total</b>	<b>9,800</b>	<b>8,300</b>	<b>15,939</b>	<b>27</b>	<b>4,325</b>						<b>189</b>	<b>468</b>	<b>1,172</b>	<b>1,828</b>	<b>2,660</b>
% Inc												147	150	56	45
<b>UBI strip Sales to LifeScan<sup>7</sup></b>											<b>127</b>	<b>221</b>	<b>399</b>	<b>530</b>	<b>600</b>
% Inc												73	81	33	13

**UBI - Forecasts**

Verio Sales	Revenue <sup>8</sup>					EBIT <sup>9</sup>					Margin				
	CY 11	CY 12	CY 13	CY 14	CY 15	CY 11	CY 12	CY 13	CY 14	CY 15	CY 11	CY 12	CY 13	CY 14	CY 15
	US\$m	US\$m	US\$m	US\$m	US\$m	US\$m	US\$m	US\$m	US\$m	US\$m	%	%	%	%	%
Product Sales <sup>7</sup>	11.5	19.9	35.9	47.7	54.0	2.0	4.0	7.2	9.5	10.8	17.5	20.0	20.0	20.0	20.0
Service Revenue - Strips	1.9	4.7	11.7	18.3	26.6	1.9	4.7	11.7	18.3	26.6					
Service Revenue - R&D	2.0	2.5	2.5	3.0	3.0	0.4	0.6	0.6	0.7	0.7	20.0	24.0	24.0	21.7	23.3
<b>Total</b>	<b>15.4</b>	<b>27.1</b>	<b>50.1</b>	<b>69.0</b>	<b>83.6</b>	<b>4.3</b>	<b>9.3</b>	<b>19.5</b>	<b>28.5</b>	<b>38.1</b>	<b>28.0</b>	<b>34.2</b>	<b>38.9</b>	<b>41.3</b>	<b>45.6</b>

Source : Industry Sources and Veritas Forecasts

Assumes <sup>1</sup> Test Strip market comprises 85-90% of Total Market

<sup>2</sup> Average Price per strip sold of \$0.55

<sup>3</sup> Initial 20% of LifeScan Sales on Country Launch - to fill supply chain

<sup>4</sup> US Launch Q3 CY2011

<sup>5</sup> Other European Launch Q3 CY2012

<sup>6</sup> ROW Launch Q1 CY2013

<sup>7</sup> Covers Europe, ROW & Australia, up to a maximum of 600m

<sup>8</sup> Strip sales to LifeScan at 9c / strip,

<sup>9</sup> Strip margin of 1.5c /strip

## Blood Coagulation Testing Market - Siemens Agreement

**Partnership with Siemens in blood coagulation meter systems**

On 9/9/11, UBI announced a Collaboration Agreement with Siemens Healthcare Diagnostics, forming a strategic partnership for the development and commercialization of products for the Point-of-Care coagulation testing market.

The basis of this agreement is:

**To cover the major hospital and ambulatory sectors**

- UBI will develop a range of test strip and reader (meter) products for the blood coagulation market for the hospital and ambulatory (surgery and clinics) sectors. The first product will be a slightly modified version of UBI's PT/INR test system (mainly around product specifications) to be followed by other tests.
- UBI will manufacture and supply the test strips for each test to Siemens. While UBI will develop the meter, Siemens will be responsible for manufacture and supply of the meter. While there is provision in the agreement for Siemens to take over manufacturing, a profit sharing arrangement with Siemens would ensure no reduction in relative earnings.
- Siemens will register, market and sell each testing system globally.
- UBI will receive an initial US\$3m payment (we were expecting \$2.0m) and 6 milestone payments (undisclosed) relating to feasibility, regulatory submissions and the launch of products. While the milestone for PT/INR payments will be significant, we would expect them to be around half the US\$17.5m received from LifeScan. We would also expect other milestone payments with the development of other blood coagulation tests for Siemens.

**UBI to receive substantial milestone payments**

This agreement is an important announcement for UBI, as:

**Agreement gives UBI entry to a further POC market**

- It gives UBI entry into the Point-of-Care coagulation testing market, estimated in 2008 at US\$750m, but expected to grow rapidly to a forecast \$1.3b in FY2020. Within this wider market, the relevant market for UBI is now around US\$600m, with the hospital and clinical sector comprising around US\$500m, but expected to grow to US\$1,050m by 2020.

**Blood Coagulation a more profitable segment**

- The model for blood coagulation is more profitable for UBI with margins likely to exceed 40%, as UBI will initially be the sole manufacturer of strips and totally controls the Intellectual Property.

**Siemens a global healthcare leader**

- Siemens is a major global healthcare leader, especially in the haemostasis (blood clotting) market. This will enable Siemens to register and market the testing system globally. Siemens has also identified a number of other non-warfarin testing areas in the blood coagulation market.
- This agreement validates UBI's R&D and commercialisation program outside of diabetes.

With the above agreement and the required modifications to the meter systems, we don't expect UBI/Siemens to apply for regulatory approval until mid CY2012, either in the EU or USA, although EU entry may be faster with Self Certification.

The regulatory filing will be based on a clinical study comparing its prototype PT/INR system with Roche CoaguChek XS (the market leader) in the US, which demonstrated a strong performance correlation and reproducibility of results.

## The Self Testing Market

**UBI to identify partners in the escalating patient self-testing segment**

The Siemens agreement excludes the patient self-testing coagulation market, the smallest but fastest growing segment, expected to grow from around \$100m currently to \$250m by 2020, with the increased convenience and the lower cost of self-test. While there are a range of PT tests currently available, only a few are cleared for patient self-testing.

As the participants in the self-test market are different from the Hospitals and Ambulatory segments, an area where Siemens is not represented, UBI is looking for separate arrangements on the basis of either:

- A global partner who would look to expand into non represented key markets.
- Individual partners in key countries or regions.

This may result in additional milestone payments, depending on the final partnership arrangements.

## The Blood Coagulation Market

The first product for Siemens will be a modified version of UBI's recently developed PT/INR test strip and meter. The PT/INR meter and strip developed by UBI performs a prothrombin time (PT) assay on a fingerprick blood sample to measure the clotting tendency of blood, reporting the result as an International Normalised Ratio (INR), to support immediate therapy or dose adjustments for anticoagulants.

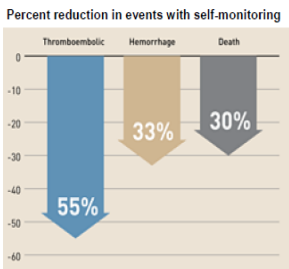
While the PT test can be used for a number of screenings (hereditary deficiencies, lupus anticoagulants and vitamin K deficiency), the test is mainly used by patients measuring the level of blood thinners, such as warfarin in the blood stream, ensuring levels remain within a target therapeutic range (TTR).

The meter and strips use a similar technology to the blood glucose meter, process and algorithms, based on patents owned by UBI. UBI commenced development in early 2005, developing a prototype in CY2010.

The advantages of the test are:

- The ability to test more often with faster results, allowing continual monitoring and the maintenance of patients on a safe and effective dose. Too much warfarin in the blood stream increases the risk of serious bleeding events, while too little increases the risk of thrombosis. A review of anticoagulation self-monitoring results has shown a 55%, 33% and 30% reduction in the incidence of Thromboembolic, Haemorrhage and Death.
- It allows physicians to adjust patient doses for diet and lifestyle change.
- Cost advantages, both in terms of reduced length of stay in emergency rooms and ongoing testing.

A clinical study comparing its prototype PT/INR system with Roche CoaguChek XS (the market leader) in the US and Australia demonstrated a strong performance correlation and reproducibility of results.

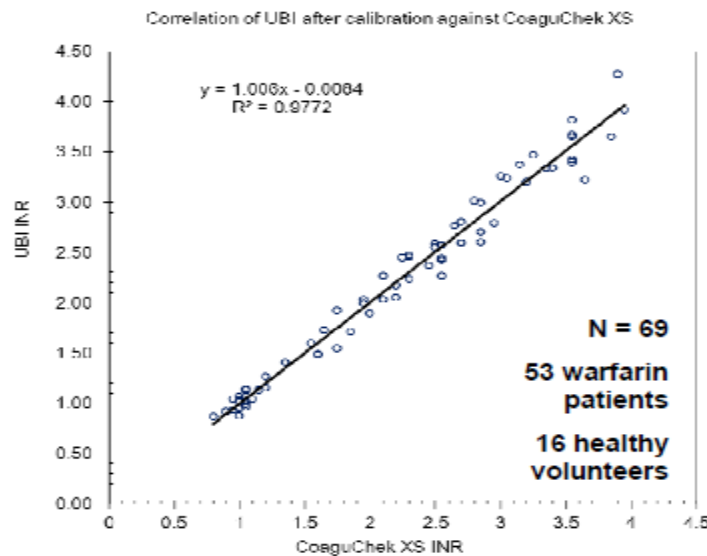


Heneghan C, Alonso-Coello P, Garcia-Alamino JM, et al. Self-monitoring of oral anticoagulation: a systematic review and meta-analysis. *Lancet*. 2006;367:404-411.

Product has high performance correlation with category leader



## Correlation: UBI & CoaguChek XS®



Source: UBI

UBI will look to a regulatory filing of the meter system either in the EU or USA in mid CY2012, although EU entry may be faster with Self Certification based on the above clinical study.

**Blood coagulation market growing at 12% pa**

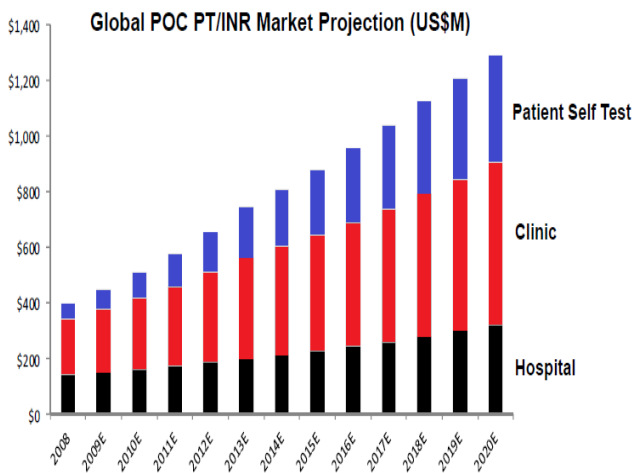
**Market Size**

Coagulation is the second largest Point of Care IVD segment after blood glucose, estimated at over US\$1.0b, but growing at a compound annual rate of over 12%.

Within this market, the PT/INR sector is currently around US\$500m, but expected to reach \$1.3b by 2020. While the market can be split into 3 components, UBI's test is applicable for all 3 markets, aimed mainly at users of warfarin, ensuring warfarin levels remain within target therapeutic ranges (TTRs).

Its use has increased with:

- A change in 2007 for US Medicare reimbursement of coagulation testing for patients taking warfarin to include uses in atrial fibrillation (~2m US patients), venous thromboembolism (~2m) and mechanical heart valves (~0.4m).
- Increasing incidence of DVT and PE, with the number of patients taking warfarin continuing to grow. Within the US, 30m prescriptions for warfarin are filled annually, with nearly 2m new patients every year. There are also estimates of 1% of the population in non-developing countries taking warfarin.
- Replacement of existing technology by lower cost Point-of-Care devices.



Source: UBI

PT/INR Segments:	Hospital POC	Ambulatory	Patient Self-Testing
<b>Market</b>	• Established	• Large & fragmented	• Emerging
<b>Growth (CAGR)</b>	• 5-7%	• 13%	• >20%
<b>Leading PT Products</b>	• iSTAT • Hemochron	• CoaguChek	• CoaguChek
<b>Reimbursement</b>	• \$3-5/test	• \$3-5/test	• \$5-30/test
<b>End Users</b>	• Professional	• Professional	• Patient (physician supervised)
<b>Examples of Leading Channel Players</b>	• Abbott • Siemens • Trinity Biotech • Becton Dickinson • Danaher • bioMerieux • Ortho	• Roche • Siemens • Danaher • Alere • Arkray • Instrumentation Lab. • Becton Dickinson	• Roche • Alere • Philips • Home health care

UBI and Siemens

In discussions with other potential partners

Source: UBI

Within the POC market the PT/INR test is expected to be the fastest growing area, due to the convenience and cost. However, the growth rate will vary with regions, with a high take-up expected in the US, Sweden, Germany and the Netherlands and slower in other regions/countries. For example, it remains uncommon in the UK with only around 18,000 of approximately 1.2 million patients in 2009 using a warfarin self-test.

**Market leader achieving revenue growth of 19%**

More than 400 million PT tests worldwide are currently conducted each year. Roche's CoagChek (the market leader) increased sales by 20% in CY2009 and 19% in CY2010 to around \$370m with robust demand in the EU and expanded Medicare reimbursement for home coagulation testing in the US.

**Table 2. Potential PT/INR StripMarket (US\$m pa)**

Indicative Testing Frequency	Indicative Earnings per Strip		
	\$0.50	\$1.00	\$1.50
Once every 8 weeks (~45M tests/annum)	\$23M	\$45M	\$68M
Once every 2 weeks (~182M tests/annum)	\$91M	\$182M	\$273M
Once per week (~364M tests/annum)	\$182M	\$364M	\$546M

Source:UBI

The total potential market for PT/INR is large, with a direct earnings potential across the market of between US\$182m and US\$546m pa depending on frequency of testing and indicative earnings per strip. These estimates are based on:

- A total global Warfarin patient market of over 7m.
- A range of test frequency periods from once weekly to every 8 weeks.
- Earnings per test strip of between \$0.50 to \$1.50. This compares to a sale price of CoaguChek strips selling in the US for between US\$5 and US\$6 per test strip. In contrast the Medicare Re-imburement ranges between \$3 and \$5 for Hospital and Ambulatory and \$5.53 per Patient Self-Test.

**Market dominance by rival opens opportunities for initial penetration**

**Competition**

The main competition is from approved and marketed products and products under development, both for Point-of-Care (eg Roche Diagnostics, Alere and Abbott) and Central laboratory groups with automated analysers (Siemens, Diagnostica, Beckman Coulter and Pharmnetics) in the hospital area. The market leader in Point-of-Care is Roche CoaguChek XS with a market share of around 66%.

We believe success with further testing as development continues and Siemens as a global healthcare partner with sales and marketing expertise, there is an opportunity for UBI to achieve a significant market share following its release, based on:

- An attractive alternative, with its meter achieving a high correlation to CoaguChek in a US clinical study.
- Advantages over the present competing systems in terms of costs, size and weight and functionality.

However, as a new entrant needing to build customer confidence, the initial penetration rates are likely to be low.

**Blood Coagulation Forecasts**

While our forecasts assume initial launch in Europe in Q1 CY2013, this may be in the larger US market, depending on regulatory arrangements. These forecasts below are conservative assuming:

- Low penetration rates, despite the global position of Siemens.
- These only account for the PT/INR market and assume no market growth or the launch of other blood coagulation testing systems.
- Apply to strips only and assume no revenue contribution from meters.

**Table 3 Blood Coagulation Market - Forecasts**

Country	COAG Market CY2012 <sup>1</sup>			UBI Market Share <sup>2</sup>			Revenue <sup>3</sup>				EBIT <sup>4</sup>				Margin <sup>4</sup>		
	Total US\$m	Strips US\$m	Meters US\$m	CY13 %	CY14 %	CY15 %	CY12 US\$m	CY13 US\$m	CY14 US\$m	CY15 US\$m	CY12 US\$m	CY13 US\$m	CY14 US\$m	CY15 US\$m	CY13 %	CY14 %	CY15 %
Europe <sup>5</sup>	225	191	34	1.0	3.5	6.0	1.1	4.0	7.6		0.5	1.9	3.6	35.0	45.0	47.0	
USA <sup>6</sup>	325	276	49	0.5	3.5	6.0	0.8	5.8	9.9		0.3	2.9	4.7	35.0	45.0	47.5	
Other <sup>7</sup>	150	128	23		1.0	3.5	0.0	0.8	2.7		0.0	0.3	1.2		35.0	45.0	
<b>Total</b>	<b>700</b>	<b>595</b>	<b>105</b>				<b>2.0</b>	<b>10.6</b>	<b>20.2</b>		<b>0.8</b>	<b>5.2</b>	<b>9.5</b>		<b>48.7</b>	<b>47.0</b>	
Milestone Payments							4.0				4.0	2.5	2.5	2.0			

Source: Industry Sources & Veritas Forecasts

- Assumes <sup>1</sup> Forecast market for CY2012 with Test Strips representing 85% of Market. <sup>4</sup> Margins of 50% on Test Strips after ramp up  
<sup>2</sup> Expected UBI Penetration <sup>5</sup> Launch in Europe in Q1 CY2013  
<sup>3</sup> Partner Sales & Marketing 40% of Strips, <sup>6</sup> Launch in US in 2H CY2013  
100% of Meters (ie UBI 60% of strips) <sup>7</sup> Launch elsewhere in 1H CY 2014

We can test the forecasts in Table 2 above with reference to Table 1 at the bottom of page 4, as follows:

- Table 1 - Indicative earnings of US\$182m pa, assuming a mid-points of: testing once every 2 weeks; and indicative earnings of \$1.00 per strip.
- Table 3 – Indicative earnings of US\$180m, on the basis of an EBIT of \$18m from 10% penetration in all markets.

## Molecular Diagnostics–

### The SpeeDX Agreement

UBI has signed a non-exclusive licence agreement with SpeeDX Pty Ltd, for access to its proprietary MNAAzyme technology. The MNAAzyme technology is a technology for detecting DNA (deoxyribonucleic acid) or RNA (ribonucleic acid).

SpeeDX is an Australian medical development company focused on the development of catalytic nucleic acid enzymes for medical diagnostics. SpeeDX has a common Chairman and Non-Executive Directors (Andrew Denver and Andrew Jane) and shareholders from the original founding group of UBI.

UBI intends to combine this technology with its diagnostic biosensor technology to create a low cost Point-of-Care testing system for the rapidly growing molecular diagnostic platform, mainly in blood screening, infectious disease, genetic and oncology testing. The attraction of a Point-of-Care testing systems is:

- The results are received within minutes and the test is more convenient.
- The test cost will be substantially lower than currently through laboratories.

UBI will pay a sign-on fee to SpeeDX, milestone payments related to stages of commercialisation and ongoing royalties, although the initial payments are not likely to be substantial. While the time horizon is not clear, we would expect at least 2 years to develop the test and a prototype meter, although we would expect UBI to have done some preliminary work before committing to the deal.

The agreement with SpeeDX is positive, as:

- It expands the growth paths for UBI. This market was one of the potential markets identified by UBI after PT/INR and development of an immunoassay platform for D-dimer and CRP, and is a major global market.
- It adds to the validity of its R&D and commercialisation capability.
- It takes UBI into a strong growth and a substantially higher value market, progressing from Blood Glucose (\$0.50 per strip) to PT/INR (\$3.50 to \$5.30) to D-Dimer (around \$10) to DNA (Test cost of around \$250).

### Market Size

The molecular diagnostic market is valued by GlobalData in Nov 2009 at more than US\$3.5b and is expected to grow at a CAGR of 14% to US\$6.2b by 2015 (see table 4).

Table 5: World Molecular Diagnostics Market by Geography \$2010 (US\$m)

Region	Market Share	Sales
North America	60%	1,982
Europe	20%	660
Japan	7%	231
ROW	13%	429

Table 4: World Market for Molecular Diagnostics, 2009-2015 (US\$m)

	2009	2010	2011	2012	2013	2014	2015
Blood screening	695	799	918	1,056	1,215	1,397	1,606
HIV/HCV testing	726	784	847	915	988	1,067	1,152
STD testing	435	487	546	611	685	767	859
Oncology testing	351	414	488	576	680	802	947
Genetic testing	357	414	480	557	647	750	870
HPV testing	267	307	353	406	467	537	617
Hospital acquired infections	86	99	116	136	159	186	217
<b>Total</b>	<b>2,917</b>	<b>3,304</b>	<b>3,748</b>	<b>4,257</b>	<b>4,841</b>	<b>5,506</b>	<b>6,268</b>

Source: Business Insights report No. BI00021-012. 23 June 2010

While Table 4 covers the main areas, there is a growing use of molecular diagnostics in:

- The increasing use in pharmacogenomics, to reduce the drug discovery, development and approval process, including the monitoring of the therapeutic efficacy of pharmaceuticals and toxicity avoidance.
- Patient stratification including drug regime testing, therapeutic monitoring and detection of predispositions to disease.

North America is clearly the dominant market (Table 5) for tests, although Asia will show the greatest growth in the coming decade.

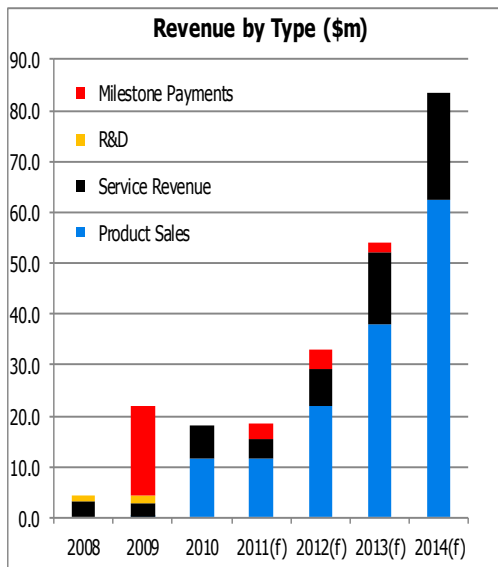
### Outlook

With the Siemens’s announcement, we have changed our forecasts to reflect:

- A later US launch, either in Q4 CY2011 or Q1 CY2012.
- A later launch of the PT/INR test, now expected in late CY2012 or early CY2013.
- Additional R&D expenses as UBI commences development work on other coagulation tests for Siemens.
- An increase in milestone payments to US\$4m in CY2012, US\$2.5m in CY2013 and CY2014, and \$2.0m in FY2015. As the timing and total amount of payments are undisclosed, we have assumed \$8.75m from Siemens for PT/INR spread over 3 years, the equivalent of 50% of the \$17.5m from LifeScan. We have also included some conservative estimates for the self-test market and additional products for Siemens.
- More conservative PT/INR penetration levels, despite Siemens as a partner.
- No inclusion for D-dimer, CRP or molecular diagnostics, although there is potential for milestone payments with the securing of sales and distribution partners and further development of the testing systems.

The main drivers of Revenue growth over the next 4 years will be:

- Growth in receipts from LifeScan with:
  - Higher Product Sales with increasing deliveries to LifeScan, from an expected US launch and increased European sales. While not certain, LifeScan have publicly stated that they expect to launch in CY2011, when it receives the imminent FDA approval for an upgraded meter. The new meter would be the basis of a US launch and increased promotion in Europe.
  - Launch by LifeScan into other new countries or regions.
  - Increased royalty revenue with increased strip sales and higher R&D revenue with the startup of some new programs for LifeScan.
- The launch of the PT/INR test and the development of any subsequent products for Siemens.



Source : UBI (Historical) & Veritas Securities (Forecasts)

Meanwhile the main drivers of Profit growth will be:

- Volume growth and economies of scale in manufacturing of strips for LifeScan.
- Increasing royalty sales on the sale of strips by LifeScan.
- The ramp-up of manufacturing for Siemens and milestone payments from Siemens. We expect the margins for the PT/INR product to be substantially higher once manufacturing is established.
- Increases in interest received as UBI moves to a cash flow positive position in CY2013.

### Valuation

We have a Discounted Cash Flow valuation for UBI of \$320m, or \$2.00 ps, based on forecast cash flow to 2020, using a discount rate of 12.5%. This is based on the forecasts for the Blood Glucose and Blood Coagulation systems, taking no account of other potential products.

At the current price, UBI is trading at a 50% discount to our valuation.

## Reasons To Buy

**Growth Markets** – Exposure to large rapid growth Point-of-Care Healthcare sectors, forecast to growth at around 12% pa. UBI is progressively moving to strong growth segments further up the value scale.

**Unique Technology** – UBI has a strong IP base across 44 patent families, backed by a strong R&D team, enabling it to develop a wide range of information-rich, low cost design and convenient Point-of-Care testing systems.

**Resources** – Strong partnerships with key industry partners in the designated sectors, a successful management and Board and supportive cornerstone shareholders..

**Improving Financial Position** – With immediate escalating revenue from LifeScan, substantial global market potential over the medium term in the coagulation market and from subsequent products over the longer term.

UBI is expected to be cash flow positive and break-even on a profit basis during 2H CY2012, with strong growth in cash flow and profitability in CY2013.

**Balance Sheet Strength** - A strong Balance Sheet, with net cash of \$17.5m, to be supported by progressive milestone payments.

**Valuation** – Currently trading at a 50% discount to our valuation of \$2.02 ps.



Universal Biosensors

Current Price: \$1.00 ps

**FINANCIAL PERFORMANCE**

Year ended 31-Dec	2010A	2011E	2012E	2013E	2014E
Sales Revenue	\$m 18.2	15.4	33.0	54.6	82.1
Cost of Goods Sold	\$m -12.3	-11.5	-19.9	-31.2	-43.0
<b>Gross Operating Profit</b>	<b>\$m 5.9</b>	<b>3.9</b>	<b>13.2</b>	<b>23.4</b>	<b>39.1</b>
R&D	\$m -6.5	-9.5	-9.0	-8.5	-8.5
Administration Costs	\$m -4.2	-4.9	-5.5	-6.3	-5.5
Other	\$m 0.0	0.5	0.2	0.0	-3.4
<b>EBITDA</b>	<b>\$m -4.8</b>	<b>-10.0</b>	<b>-1.1</b>	<b>8.6</b>	<b>21.7</b>
Depreciation	\$m -3.0	-3.6	-3.7	-4.0	-4.2
<b>EBIT</b>	<b>\$m -7.8</b>	<b>-13.6</b>	<b>-4.8</b>	<b>4.6</b>	<b>17.5</b>
Interest	\$m 1.2	0.8	0.3	0.2	0.3
Pre Tax Profit	\$m -6.6	-12.8	-4.5	4.8	17.8
Tax	\$m 0.0	0.0	0.0	0.0	0.0
<b>Reported Profit</b>	<b>\$m -6.6</b>	<b>-12.8</b>	<b>-4.5</b>	<b>4.8</b>	<b>17.8</b>

**GROWTH**

	2010A	2011E	2012E	2013E	2014E
Revenue	% 320.8	-15.5	115.1	65.3	50.3
COGS	% 1857.7	-6.7	73.4	57.1	37.7
Gross Operating Profit	% -72.5	-33.9	237.4	77.8	67.2
R&D	% -56.5	46.6	-5.3	-5.6	0.0
EBITDA	% na	107.8	-88.6	-851.6	152.7
EBIT	% na	74.3	-64.4	-194.9	281.2
Reported Profit	% na	93.6	-64.5	-205.5	271.6
EPS	% na	92.2	-64.5	-205.5	271.6

**P&L RATIOS**

	2010A	2011E	2012E	2013E	2014E
Gross Operating Profit / Sales	% 32.4	25.4	39.8	42.8	47.6
EBITDA / Sales	% -26.5	-65.1	-3.5	15.7	26.5
EBIT / Sales	% -42.9	-88.5	-14.7	8.4	21.3
Effective Tax Rate	% 0.0	0.0	0.0	0.0	0.0
Interest Cover	x na	na	na	na	na

**Per SHARE**

	2010A	2011E	2012E	2013E	2014E
Issued Shares (Wt Avg)	m 157.6	158.8	158.9	158.9	158.9
EPS	¢ps -4.2	-8.1	-2.9	3.0	11.2
Operating Cash Flow ps	cps -4.1	-4.5	-1.2	4.2	12.0
Free Cash Flow	¢ps -5.5	-5.7	-2.4	3.0	10.7
DPS	¢ps 0.0	0.0	0.0	1.0	4.0
Franking	% 0.0	0.0	0.0	0.0	0.0
Dividend Payout Ratio	% 0.0	0.0	0.0	33.1	35.7

**PARAMETERS**

	2010A	2011E	2012E	2013E	2014E
PE Ratio	x -36.2	-12.4	-35.0	33.1	8.9
Enterprise Value / EBITDA	x -28.2	-14.5	-129.9	16.7	5.9
Enterprise Value / Profit	x -20.5	-11.3	-32.7	30.0	7.3
Cash Flow ratio	x -37.3	-22.4	-86.2	23.7	8.4
Dividend Yield	% 0.0	0.0	0.0	1.0	4.0

**SEGMENTS**

	2010A	2011E	2012E	2013E	2014E
<b>Sales Revenue</b>					
Product Sales	\$m 11.8	11.5	21.9	37.9	58.3
Service Revenue	\$m 6.4	3.9	7.2	14.2	21.3
R&D	\$m 0.0	0.0	0.0	0.0	0.0
Milestone Payments	\$m 0.0	0.0	4.0	2.5	2.5
<b>EBIT</b>					
Product Sales	\$m 1.0	2.0	4.0	7.9	14.2
Service Revenue	\$m 4.9	1.9	4.7	11.7	18.3
R&D	\$m -6.5	-9.5	-9.0	-8.5	-8.5
Milestone Payments	\$m 0.0	0.0	4.0	2.5	2.5
Corporate	\$m -7.2	-8.0	-8.5	-9.0	-9.0
<b>EBIT Growth</b>					
Product Sales	% na	109.3	98.1	98.1	80.7
Service Revenue	% 84.2	-61.7	147.4	150.3	56.0
R&D	% -52.2	46.6	-5.3	-5.6	0.0
<b>EBIT Margin</b>					
Product Sales	% 8.2	17.5	18.2	20.8	24.4
Service Revenue	% 76.9	48.6	65.2	82.4	85.9

Source: UBI (Act) and Veritas Securities (Est)

**CASH FLOW**

Year ended 31-Dec	2010A	2011E	2012E	2013E	2014E
<b>Operating EBITDA</b>	<b>\$m -4.8</b>	<b>-10.0</b>	<b>-1.1</b>	<b>8.6</b>	<b>21.7</b>
Net Interest Received/Paid	\$m 1.2	0.8	0.3	0.2	0.3
Tax Paid	\$m 0.0	0.0	0.0	0.0	0.0
Change Working Capital	\$m -4.7	2.1	-1.0	-2.1	-3.0
Other	\$m 1.9	0.0	0.0	0.0	0.0
<b>Operating Cash Flow</b>	<b>\$m -6.4</b>	<b>-7.1</b>	<b>-1.8</b>	<b>6.7</b>	<b>19.0</b>
Capex	\$m -2.3	-2.0	-2.0	-2.0	-2.0
<b>Free Cash Flow</b>	<b>\$m -8.7</b>	<b>-9.1</b>	<b>-3.8</b>	<b>4.7</b>	<b>17.0</b>
Acquisitions/Asset Sales	\$m 0.0	0.0	0.0	0.0	0.0
Dividends Paid	\$m 0.0	0.0	0.0	0.0	-2.4
Equity Change	\$m 0.7	0.1	0.0	0.0	0.0
Debt Change	\$m 0.0	0.0	0.0	0.0	0.0
<b>Change in Net Cash</b>	<b>\$m -8.0</b>	<b>-9.0</b>	<b>-3.8</b>	<b>4.7</b>	<b>14.6</b>

**BALANCE SHEET**

	2010A	2011E	2012E	2013E	2014E
Cash	\$m 23.3	14.2	10.4	15.1	29.7
Receivables	\$m 3.6	4.0	6.0	8.0	10.0
Inventory	\$m 3.2	4.0	6.0	7.5	11.0
Other Current Assets	\$m 0.7	0.8	0.9	1.0	1.0
<b>Current Assets</b>	<b>\$m 30.7</b>	<b>23.0</b>	<b>23.3</b>	<b>31.6</b>	<b>51.7</b>
Property, Plant & Equipment	\$m 21.1	19.5	17.8	15.8	13.6
Intangibles	\$m 0.0	0.0	0.0	0.0	0.0
Other NC Assets	\$m 0.0	0.0	0.0	0.0	0.0
<b>Non Current Assets</b>	<b>\$m 21.1</b>	<b>19.5</b>	<b>17.8</b>	<b>15.8</b>	<b>13.6</b>
<b>Total Assets</b>	<b>\$m 51.8</b>	<b>42.6</b>	<b>41.1</b>	<b>47.4</b>	<b>65.4</b>
Payables	\$m 1.8	5.1	8.1	9.5	12.0
Current Debt	\$m 0.0	0.0	0.0	0.0	0.0
Other Current Liabilities	\$m 2.7	3.5	4.5	6.0	6.5
<b>Current Liabilities</b>	<b>\$m 4.5</b>	<b>8.6</b>	<b>12.6</b>	<b>15.5</b>	<b>18.5</b>
Non Current Debt	\$m 0.0	0.0	0.0	0.0	0.0
Other NC Liabilities	\$m 2.2	1.5	0.6	-0.8	-1.3
<b>Non Current Liabilities</b>	<b>\$m 2.2</b>	<b>1.5</b>	<b>0.6</b>	<b>-0.8</b>	<b>-1.3</b>
<b>Total Liabilities</b>	<b>\$m 6.6</b>	<b>10.1</b>	<b>13.2</b>	<b>14.7</b>	<b>17.2</b>
<b>Shareholder Funds</b>	<b>\$m 45.2</b>	<b>32.5</b>	<b>27.9</b>	<b>32.7</b>	<b>48.2</b>

**BALANCE SHEET RATIOS**

	2010A	2011E	2012E	2013E	2014E
Receivables turn	x 9.1	4.0	6.6	7.8	9.1
Inventory turn	x 7.0	3.2	4.0	4.6	4.6
Net Debt	\$m 0.0	0.0	0.0	0.0	0.0
Gearing (D:D+E)	% 0.0	0.0	0.0	0.0	0.0
Current Ratio (CA / CL)	x 6.9	2.7	1.8	2.0	2.8
Net Assets	¢ps 28.5	20.4	17.6	20.6	30.3
Net Tangible Assets	¢ps 28.5	20.4	17.6	20.6	30.3
Cash	¢ps 14.7	9.0	6.5	9.5	18.7
Price to Book Value	x 3.5	4.9	5.7	4.9	3.3
Return on Assets	% -14.5	-28.8	-11.6	10.4	31.1
Return on Equity	% -13.7	-33.0	-15.0	15.8	44.1

**VALUATION**

Valuation Method	\$	Premium/Discount (%)
DCF	2.02	50.4
Current Price	1.00	

**MAJOR SHAREHOLDERS**

Directors	m	14%
Johnson & Johnson	m	11%
CM Capital Investments	m	11%
PFM Cornerstone	m	7%
Top 20 (16/3/2011)	m	70%

**DIRECTORS**

Andrew Denver	N-E Chair	Andrew Jane	N-E Dir
Paul Wright	MD & CEO	Dr Jane Wilson	N-E Dir
Dr Colin Adam	N-E Dir	Marshall Heineberg	N-E Dir
Denis Hanley	N-E Dir		

**Sales**

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 Tony Bonello +61 2 8252 3230  
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 Patrick Ford +61 2 8252 3211  
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 Nelson Peace +61 2 8252 3285  
 Clay Melbourn +61 2 8252 3220  
 Bryce Reynolds +61 2 8252 3215  
 Stephen Murphy +61 8 9380 8351

**Research**

**Industrials**  
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 Levi Hawker +61 3 8676 0689

**Resources**  
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 Matt Baillie +61 2 8252 3275

**RATING**

BUY – anticipated stock return is greater than 10%  
 SELL – anticipated stock return is less than -10%  
 HOLD – anticipated stock return is between -10% and +10%  
 SPECULATIVE – High risk with stock price likely to fluctuate by 50% or more

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