

Universal Biosensors Ltd

Equity raising to accelerate growth opportunities

On 26/11/12, UBI completed a \$12m institutional placement, comprising 13.3m shares at \$0.90 ps, to be followed by a Share Purchase Plan of up to \$15,000 per shareholder at a similar price. The raising will initially increase cash on the Balance Sheet to around \$26m, with the funds raised to be used to:

- Accelerate the development of its current Point-of-Care testing opportunities, particularly patient self-test PT-INR, immunoassay and molecular diagnostic testing systems.
- To provide working capital to support the launch of these new products and growth in manufacturing.
- Provides flexibility in funding and structuring of opportunities, based on its proven technologies.

These additional testing systems can become substantial contributors, some exceeding returns from blood glucose, as:

- They have greater involvement in the value chains, covering meter supply and total strip manufacture and supply.
- These additional tests generate higher unit revenue and margins.
- The success and validation of its technology with blood glucoses and blood coagulation, gives access to a wider high quality partner opportunities and increased leverage.

Improving Operating Base

Operating Profit continues to improve with a strong Q3 and YTD Operating Profit of \$1.9m and \$4.7m, supported by continued growth in Blood Glucose from product sales and service fees and Milestone Payments from Siemens.

The increasing profitability of the Blood Glucose sector and the anticipated launch of Blood Coagulation will move UBI to a Cash Flow positive and Net Profit position over the next 2 years, outweighing increased R&D costs.

However, growth will accelerate in CY2015 onwards, driven by the non-blood glucose testing systems, as the PT-INR blood coagulation increases penetration and the two further tests are released, and development of Immunoassay and Molecular Diagnosis tests is completed and launched.

Reasons to BUY

Growth Markets – Exposure to large rapid growth Point-of-Care Healthcare sectors, estimated at US\$15b, growing at 11% pa, with a strong position in the Blood Glucose market and imminent launch of the Blood Coagulation market.

Industry Position – Leading edge technology and a strong IP position, backed by a strong R&D team and validated by key international healthcare groups.

Resources – A modern approved plant capable to supplying UBI requirements for the foreseeable future, backed by successful management and Board.

Development Pipeline – A further 3 projects under development.

Strong Financial Position – Expected to be Cash Flow positive and profitable towards the end CY2013, supported by a strong Balance Sheet, now with Cash of \$26m.

Valuation – Currently trading at a 45% discount to our valuation of \$1.65ps.

UBI.ASX

BUY

29 November 2012

Price	\$0.91
Price Target	\$1.65
Valuation method	DCF
GICS sector	Healthcare
12 Mth Price Range	\$0.52 - 1.15
Avg monthly t/o	2.4m
Market Capitalisation	\$165m
Shares on issue	181m
Options on Issue	10m
Enterprise value	\$140m
Previous rating	BUY

Year Ended Dec 30		10A	11A	12E	13E	14E
Revenue	\$m	18	14.7	29.7	43.8	69.9
EBITDA	\$m	-4.8	-12.1	-5.7	-2.1	15.4
EBITDA margin	%	32.4	11.4	38.5	40.8	50.6
EBIT	\$m	-7.8	-15.4	-8.4	-5.0	12.4
EBIT margin	%	-42.9	-104.8	-28.3	-11.4	17.7
NPAT	\$m	-6.6	-14.7	-8.0	-4.4	13.1
EPS growth	%	-560.5	120.2	na	-50.4	-394.2
DPS	¢ ps	0.0	0.0	0.0	0.0	2.0
Franking	%	0.0	0.0	0.0	0.0	0.0
PER	x	na	na	na	-37.1	12.6
Dividend yield	%	0.0	0.0	0.0	0.0	2.2
NTA/share	¢ ds	29.7	22.0	25.1	22.7	30.0
EV/EBITDA	x	-25.2	-10.7	na	-66.8	8.3
Gearing (D:E)	%	0.0	0.0	0.0	0.0	0.0
P/OCF	x	-37.3	-20.2	na	-39.8	11.7
ROA	%	-14.2	-31.1	-15.6	-8.0	17.7
ROE	%	-13.4	-35.7	-19.9	-10.2	27.4
Interest cover	x	na	na	na	na	na

UBI v XSI (S&P/ASX Small Industrial Index)



Activities

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

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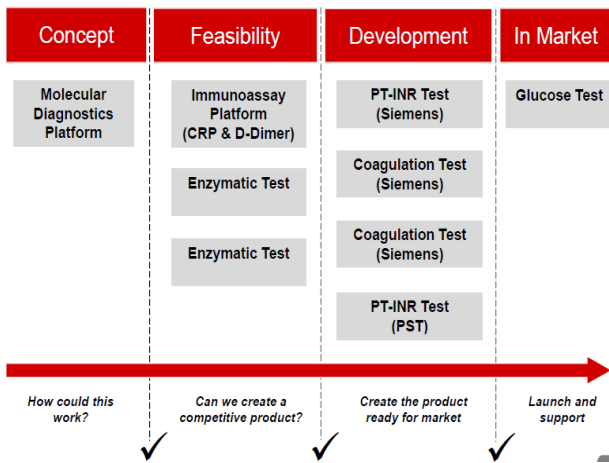
Equity Raising

On 26/11/12, UBI completed a \$12.0m institutional placement, comprising 13.3m shares at \$0.90 ps, to be followed by a Share Purchase Plan (SPP) for \$15,000 per eligible shareholder at a similar price. While the SPP will be capped at UBI’s discretion, we would expect an additional raising of around \$6m.

The institutional raising will increase net cash to around \$26m (\$32m with our estimate of \$6m raided by the SPP), the funds raised to be used to:

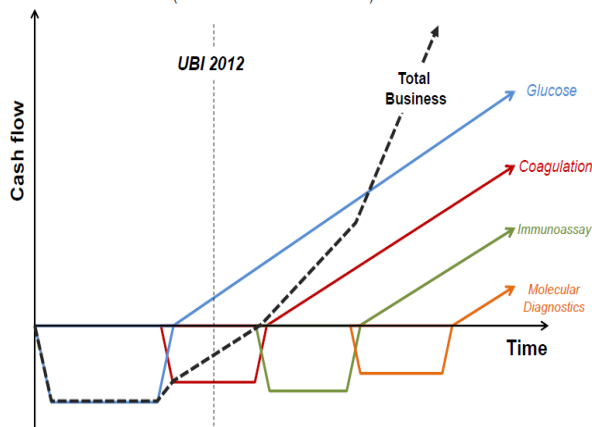
- Support and accelerate new product development, specifically:
 - The PT-INR patient self-test, including completion of development of a strip and meter systems, funding production and inventory for regional/global rollouts (see page 4).
 - Continue the development of the immunoassay test platform, particularly CRP and D-dimer, which demonstrate commercial feasibility in CY2012 (see page 4 and 5).
 - Further develop the Molecular Diagnostics test platform, currently in concept stage, but expected to demonstrate feasibility in CY2013 (See Page 6)
- Flexibility to develop testing systems further before partnering and to take advantage of market driven opportunities.
- Providing additional working capital to support growth, particularly glucose and coagulation test strip manufacture and the new product launches.

Pipeline of future POCD products



Source: UBI

Diagnostic Business Schematic (indicative cash flow vs time)

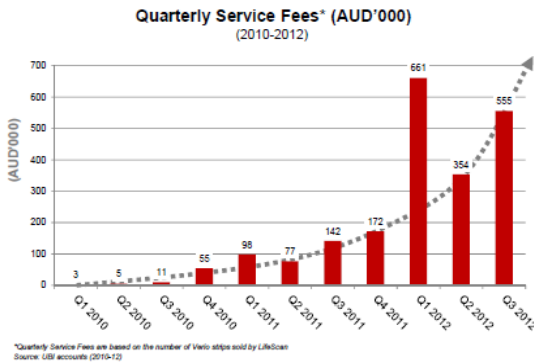


Source: UBI

The raising is vital in accelerating the development of UBI’s Point of Care diagnostics business, as:

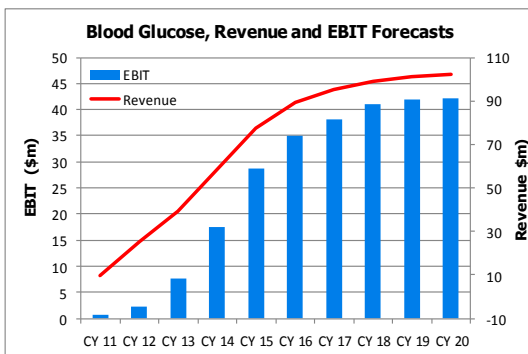
- Development to date has been financed by funds raised in the initial IPO and milestone funding from its partners, LifeScan and Siemens.
- UBI is at a pivotal stage in developing its presence in the global Point of Care diagnostics sector, with its electro chemical technology validated by:
 - The launch of the Verio blood glucose testing system by LifeScan in global markets and a US\$4.5m R&D project for a related strip based testing system.
 - The development and manufacturing agreement with Siemens covering three blood coagulation testing systems, with the first product to be launched in CY2013.
- There are opportunities to leverage on the above success, with:
 - The launch in the home point of care markets for blood coagulation.
 - The opportunity to finalise the feasibility and move to the development stage in immunoassay for CRP and D-Dimer, as well as investigating other opportunities in immunoassay.
 - Confirmation of feasibility in Molecular Diagnostics testing.
 - Opportunities for other enzymatic testing systems based on the success with blood glucose and blood coagulation.
- These additional products will generate higher economic returns, through:
 - Greater involvement in the value chains, covering meter supply and total strip manufacture and supply.
 - These additional tests generate higher unit revenue and margins, with reimbursements increasing from \$0.50 per test for Blood Glucose and \$5.53 per test for PT-INR to a prospective range of \$8 for CRP to \$250 for Molecular Diagnostics (DNA).

Blood Glucose to generate rapidly escalating cash flow



Blood Glucose will be the short term driver of revenue and profit growth for UBI on the back of:

- Continued growth in service revenue of US1.0¢ per strip from LifeScan’s strip sales, following the launch in Europe in CY2011 and North America in early CY2012, with:
 - The progressive substitution of Verio into LifeScan’s customer base covering over 4bn strips pa. Based on Q3 CY2012 sales of 55.5m strips, or 222m pa, the current penetration is between 5.0% and 5.5%.
 - The potential for LifeScan to increase market share above the current 27%, on the back of Verio.
 - Continued growth in the blood glucose testing market of around 10% pa.
- Further strip sales to LifeScan, increasing to around 600m (total capacity of 750m), despite a ramp-up in manufacture from LifeScans’s own plant.
- Further development work for LifeScan.



Using a diffusion curve based on previous changes in meter systems to forecast total strip sales, we expect Revenue and EBIT to increase strongly through to CY2018 at \$99.1m and \$54.3m. Beyond CY2019, we expect revenue to increase in line with the service revenue of US1.0¢ per strip.

Source: Veritas Forecasts

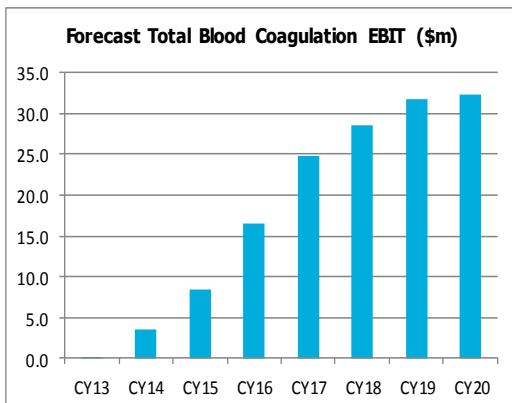
Launch of Blood Coagulation the next major profit driver

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

At over US\$885m in 2010, the blood coagulation test market is the second largest segment of the US\$15.5m Point of Care Diagnostic, supported by a global anticoagulant drug market valued in 2012 at around US\$5.7b.

The test market is growing at a compound growth rate of 8%, as a result of:

- An increasing and aging population and increasing use of warfarin, with over 7m users.
- An increasing testing regime, with the benefits of regular testing, helped by an increase in US Medicare re-imburement, now at \$5.53 per test.



Within the blood coagulation sector, the PT/INR test is the largest, currently around 80% (US\$700m) of the total, with strips comprising 85% (US\$600m) or around 110m strips pa. Within the PT/INR market, the Hospital and Ambulatory (clinic/physician/pharmacy) markets being targeted by Siemens are around \$560m.

We expect Siemens to launch the PT-INR test in CY2013, initially in Europe, where it can self-certify and Siemens has a strong competitive position. We would expect US launch later in CY2013, following FDA approval.

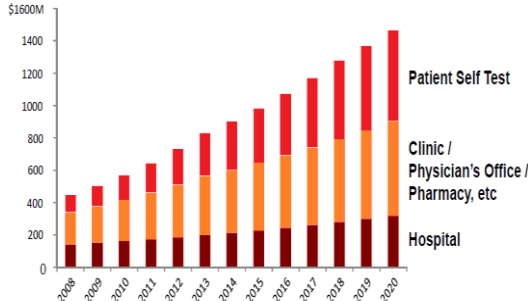
Based on a testing regime of once every 2 weeks and an earnings per strip of \$1.0 per strip, UBI estimate the total market at \$182m.

With Roche dominating the total sector the ambulatory and self-testing segments, with a market share of over 60%, we expect Siemens to obtain a market share in hospital and ambulatory of around 20% in CY2019.

Source: Veritas Forecasts

Patient Self-test, the next Opportunity

Global POC PT/INR Market Projection (US\$M)



Source: Management estimates, Kalorama, The Worldwide Market for In Vitro Diagnostic Tests, 6th Ed., 2008; Timark, "Point of Care Diagnostic Testing World Markets", April 2011

UBI has retained the rights to the patient self-test market, currently the smallest area at around \$200m, but growing at a compound rate of 20%, expected to reach US\$600m by 2020.

UBI is in discussion with potential partners, most likely regional. The participants in the self-test market are different from the Hospitals and Ambulatory segments, an area where Siemens is not represented,

UBI will use some of the raising to complete development of a meter and fund meter manufacture and inventory. However, we would not expect a launch of the self –test until CY2014. As UBI is responsible for manufacturing and inventory, we would expect margins to be substantially higher, possibly 70% to 75%.

Immunoassay Opportunities

Immunoassay is the measurement of blood borne biomarkers using ligand binding, the measurement of enzyme activity and other techniques.

1. C-reactive protein (CRP)

CRP tests are used in systemic inflammation cases, testing for elevated C-reactive protein (CRP) in the blood serum through the presence of key inflammatory cytokines. Key diseases include atherosclerosis, rheumatoid arthritis and other autoimmune diseases, cancer, COPD and Alzheimer’s disease, as well as a potential indicator of cardiac risk, therapy effectiveness and bacterial infection.

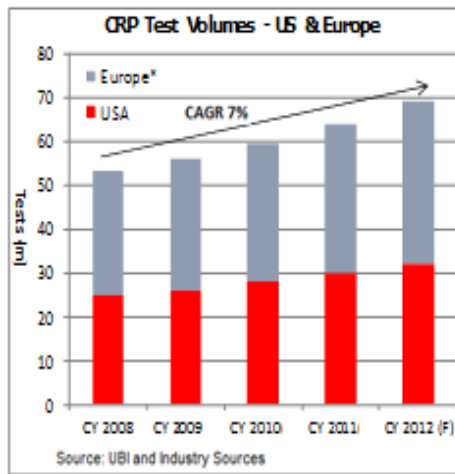
The CRP tests are increasing in importance, with a number of drug companies now developing products to address the inflammatory component of certain autoimmune diseases (rheumatoid arthritis) and a range of cancers, including multiple myeloma and pancreatic cancer. As millions of patients worldwide are affected by these conditions, the accurate monitoring of C-reactive protein levels at the point-of-care would be valuable in managing these patients.

It is estimated that around 80m pa CRP tests were conducted globally, growing at a CAGR of 7%, with around 70m in the US and Europe. US reimbursements range from \$8.0 per test for the more common low level to \$19.00 for a high level test.

The CRP test is well accepted in the US and reimbursed by Medicare and other health insurance companies, with the current US market estimated at US\$350m. However, there is no direct reimbursement in Europe, except for Scandinavia. Globally, Scandinavia is an important and the fastest growing market, conducting 7m to 8m tests in CY2011, due to a high level of acceptance among GPs and specialists use in monitoring antibiotic usage.

However, the Point-of-Care market is underdeveloped, comprising only 5% to 6% of US tests, compared to Scandinavia which conducts around 35% of global POC.

A CRP meter system would face competition from Cholestech (Alere) Roche Diagnostics, Orion Corporation and Axis Shields plc, and automated analysers, mainly in central laboratories.



Source: UBI and Industry Sources

* Europe comprises Germany, UK, France, Italy, Spain & Scandinavia

D-dimer

D-dimer tests are used to detect hypercoagulability and monitor conditions associated with thrombotic disease. A positive test indicating a high level of fibrin degradation may be associated with deep vein thrombosis (DVT) and pulmonary embolism (PE). The incidence of thrombotic disease continues to increase with aging and is associated with rising mortality in Western society.

The advantages of the test are:

- It eliminates the use of Spiral CT VQ scans, linked to an increased incidence of cancer.

- The ability to test more often with faster results.
- It reduces length of stay in emergency rooms.

The incidence of thrombotic disease continues to increase with aging and is associated with rising mortality in Western society.

D-dimer test is one of the fastest growing laboratory tests globally. In CY2008 an estimated 27m to 29m D-dimer tests were conducted in the US and Europe, with expectations of CAGR of 10% to 39m to 41m in CY2012.

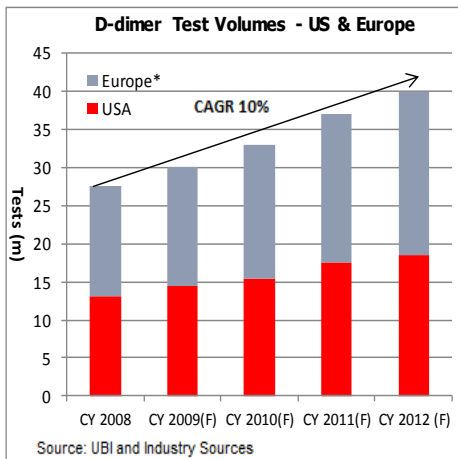
While Europe is the largest market, conducting around 45% of global tests, due to a high level of acceptance by physicians, the US is an important market, due to its size and reimbursement by Medicare and other health organisations.

Based on a US Medicare Re-imbursements of around \$14.40 per test, the current market is around US\$550m, split US\$250m in the USA and \$300m in Europe.

Due to the links with blood coagulation, UBI have granted Siemens the 'right of first bid'. Any developed product would compete with path labs and existing competitors such as Biosite (Alere inc) and pathology laboratories, such as Siemens, Roche, Instrumentation Laboratory, Diagnostica Stago and Biomerieux.

Other Immunoassay

We expect UBI to use success with CRP and D-Dimer as a leverage platform to develop new immunoassay tests.



* Europe comprises Germany, UK, France, Italy, Spain & Scandinavia

Other Enzymatic Tests

Potential for other enzymatic tests

With success of UBI with Blood glucose and blood coagulation, it has received interest from a number of major healthcare groups with view to using its technology to develop other enzymatic Point of Care tests.

We would expect similar arrangements to blood coagulation, with some upfront funding and milestone payments.

Molecular Diagnostics – the Blue Sky

Development of Molecular Diagnostics centred on UNI and SpeeDX platforms

UBI intends to use its diagnostic biosensor technology with the in-licensed MNAAzyme technology from SpeeDX Pty Ltd to create a low cost Point-of-Care testing system, using a portable strip and meter system or the rapidly growing molecular diagnostic platform, mainly in blood screening, infectious disease (HIV/HCV, STD and hospital acquired infections), genetic and oncology testing.

SpeeDX 's proprietary MNAAzyme technology, around the use of catalytic nucleic acid enzymes for medical diagnostics, mainly in detecting DNA (deoxyribonucleic acid) or RNA (ribonucleic acid).

The attractions of a Point-of-Care testing systems are:

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

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. This growth is due to:

- An aging population and greater incidence of chronic disease, such as cancer.
- The need for earlier diagnosis and faster treatment to reduce healthcare costs.
- Improved understanding of the human genome
- Advances in chemistry and instrumentation technology.

While the main markets are the US at around 60% of the global market, followed by Europe at 20%, Asia is expected to show the greatest growth in the coming decade.

Potential market of US\$6.2b by 2015

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

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

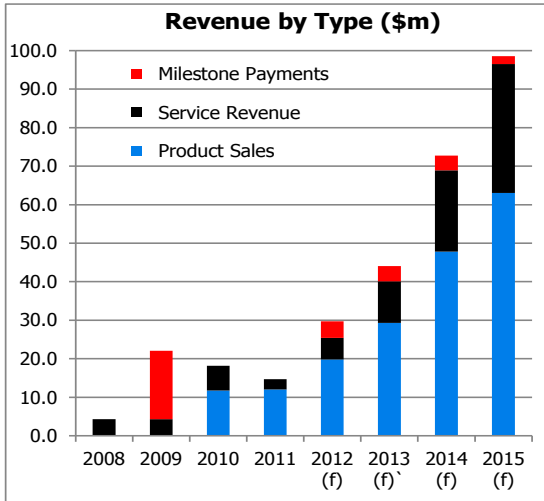
	2009	2010	2011	2012	2013	2014	2015
Blood screening	695	799	918	1,056	1,215	1,397	1,606
HIV/HCV testing	726	784	847	915	988	1,067	1,152
STD testing	435	487	546	611	685	767	859
Oncology testing	351	414	488	576	680	802	947
Genetic testing	357	414	480	557	647	750	870
HPV testing	267	307	353	406	467	537	617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

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

While the above table covers the main areas, there is a growing use of molecular diagnostics 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.

Forecasts



Source: Veritas Forecasts

Revised Forecasts for CY2012 to CY2015

P&L	2011E	2012F	2013F	2014F	2015F
Revenue (\$m)	14.7	29.7	43.8	69.9	96.9
% Ch		102.4	47.2	59.8	38.5
EBIT (\$m)	-15.4	-8.4	-5.0	12.4	27.6
% Ch		-45.4	-40.5	-347.1	123.6
Margin (%)	-104.8	-28.3	-11.4	17.7	28.5

Source: Veritas Forecasts

The forecasts have been adjusted for the following:

- A modest increase in revenue from the quicker launch of the blood coagulation self-test, offset by increased costs from production and inventory build ahead of supply to partners.
- An increase in R&D as a result of the increased development activity, but still within the range of \$9m to \$15m, with the level depending on success and partnership arrangements.
- A modest increase in interest received with high cash balances.

Our Forecasts are based on:

- Launch of the PT-INR in Q2 CY2013 in Europe and Q4 CY2013 in the US and other key countries.
- The remaining 2 blood coagulation tests to be launched in Q2 CY2014.
- The launch of the PT-INR home-test in Q2 CY2014.
- No inclusion of CRP and D-dimer until they move to final development. We would expect these tests to be launched in 2H CY2014.
- A raising of only \$6m from the SPP, assuming a take-up of by 50% of the 1,500 shareholders and an average take-up value of \$8,000 per holder. Levels above this would result in a higher interest received component and a lower forecast EPS in each year.

Valuation

Price Target of \$1.65 ps

We have maintained Valuation and Price Target of \$1.65 ps, based on a Sum of the Parts valuation of \$1.65 ps, although below our Discounted Cash Flow valuation of \$1.70 ps.

The Sum of the Parts valuation attributes:

- \$1.10 ps to Blood Glucose (\$1.30 adjusted for increased capital).
- \$0.30 ps to Blood Coagulation (increased with progress on home-test)
- \$0.10 ps to the Immunoassay and Molecular Diagnostics (increased with acceleration in Development).
- \$0.15 ps in Cash (expected level at December 2013).

This valuation equates to a CY2014 and CY 2015 Enterprise Value : EBITDA ratios of 16.5x and 7.5x, reasonable given the growth profile.

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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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