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Universal Biosensors (UBI)

The future of biosensors

Speculative

See key risks on Page 18 and Biotechnology Risk Warning on Page 21. Speculative securities may not be suitable for Retail Clients.

Recommendation

Buy (Initiation)

Price

\$0.80

Valuation

\$1.25

Risk

Speculative

GICS Sector

Pharmaceuticals & Biotechnology

Expected Return

Capital growth	56.3%
Dividend yield	0.0%
Total expected return	56.3%

Company Data & Ratios

Enterprise value	\$137.9m
Market cap	\$145.1m
Issued capital	178.0
Free float	99.0%
Avg. daily val. (52wk)	\$0.19m
12 month price range	\$0.58-\$1.04

Price Performance

	(1m)	(3m)	(12m)
Price (A\$)	0.95	1.00	0.50
Absolute (%)	-12.11	-16.08	68.69
Rel market (%)	-19.46	-14.69	59.72

Absolute Price



SOURCE: IRESS

Leading the field in biosensing technology

UBI is a biosensor development company that manufactures testing devices based around their unique and versatile electrochemical sensor technology, including the Sentia™ wine testing device; and the Xprecia™ series (Xprecia Stride™ and now the Xprecia Prime™) for the analysis of blood coagulation. Additionally, they are developing a range of new tests that use their proprietary electrochemical sensing technology that are likely to have a broad market.

While there is some market competition for the coagulation testing device, UBI is likely to perform as well as the current field leader and undercut that product on price by a substantial amount.

In our view, the Sentia™ wine testing device outpaces all other current market options on price, accuracy, ease of use, and size, providing a sustainable competitive advantage.

The next catalyst for the company will be results of the clinical trial for the new Xprecia Prime™ blood coagulation test device. Data off the back of this trial will support FDA approval and we expect launch of the device and associated revenue in the US in early CY23 at the latest. The device has already received the CE mark approval in Europe. UBI have recently set up 2 new distribution centres in The Netherlands and the US, with a growing team of sales representatives in both regions to facilitate expansion. Both the Sentia™ and the Xprecia™ will be distributed via these centres. The company also has a deep pipeline of additional products in development.

Investment view: Valuation \$1.25, Initiate with Buy (Spec.)

We initiate coverage with a buy (speculative) and a valuation of \$1.25 – a 56.3% expected return on the current stock price (\$0.80). Valuation is DCF driven, and incorporates conservative assumptions around uptake and sales of the two available commercial products and modest growth in laboratory services. Our forecast indicates the company is likely to be profitable by the end of FY24e, with NPAT expected to be \$7.9m at that time.

Earnings Forecast

December Year End	FY21	FY22e	FY23e	FY24e
Revenues	5.8	10.2	17.6	30.5
EBIT (A\$m)	-10.5	-7.6	-2.0	6.0
NPAT (A\$m)	-10.5	-7.7	-2.1	5.9
EPS (cps)	-5.9	-4.3	-1.2	3.3
EPS growth (%)	nm	nm	nm	nm
PER (x)	nm	nm	nm	24.2
FCF yield (%)	nm	nm	nm	nm
EV/EBIT (x)	nm	nm	nm	nm
Dividend (cps)	0.0	0.0	0.0	0.0
Franking (%)	0.0%	0.0%	0.0%	0.0%
Yield (%)	0.0%	0.0%	0.0%	0.0%
ROE (%)	-38%	-39%	-12%	25%

SOURCE: BELL POTTER SECURITIES ESTIMATES

UBI taking sample analysis into the future

Portable Analysers

Universal Biosensors (ASX:UBI) is a biosensor development and manufacturing company. Their underlying technology and expertise are in the development and manufacture of electrochemical cells used to measure specific target molecules or analytes in various sample types. The revenue model for UBI includes the sale of proprietary handheld, portable analysers along with single-use test strips that are inserted into the devices.

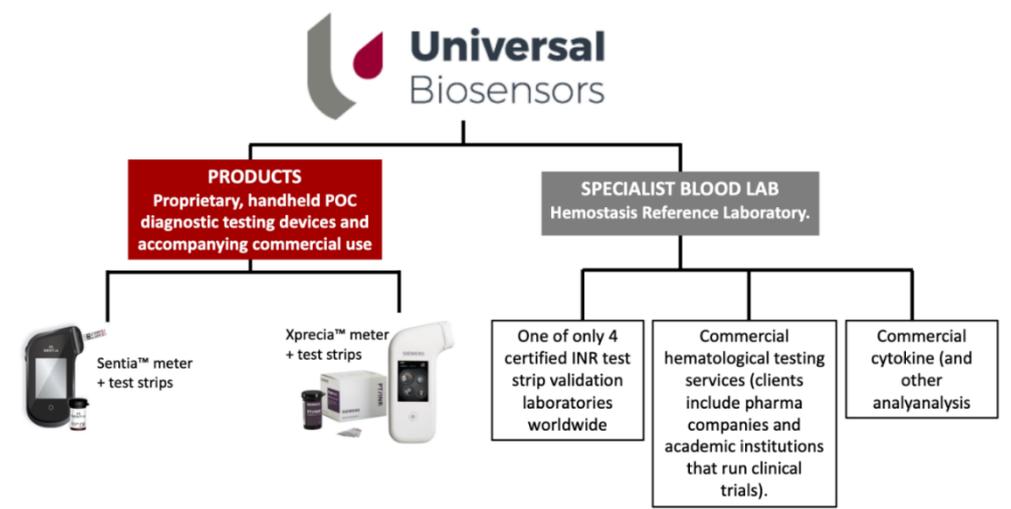
Back in 2002, UBI partnered with LifeScan – a diabetes-focussed diagnostics company that was a subsidiary of Johnson & Johnson – to develop and manufacture their first portable, handheld testing device: a blood glucometer, and the associated disposable test strips. This glucometer, the OneTouch Verio, hit the market in 2009, with UBI continuing with the manufacture of the test strips for the device (>100,000 strips per annum) until ~2014. UBI exited the partnership in 2018 following the divestiture of LifeScan, who fully acquired the asset, by J&J - but not before the device became the world-leading portable blood glucometer.

Since then, UBI has focussed on the development and manufacture of devices for new target analytes – with the demand for portable testing capabilities increasing globally.

The Hemostasis Reference Laboratory

UBI creates additional revenue income from their commercial specialist blood laboratory: The Hemostasis Reference Laboratory (HRL). UBI acquired this laboratory in 2016, having always had their PT/INR test strips calibrated there. HRL performs specialised coagulation blood testing services and is expanding into various other commercial haematological testing services as well as multiplexed immunoassays for various circulating cytokines and other analytes. These new commercial opportunities generated ~AUD\$2 million in revenue in FY21, and as COVID interruptions to clinical trials are attenuated, UBI are likely to receive even more of this revenue going forward – given their clients are pharmaceutical companies and academic and research institutions who run large clinical trials.

Figure 1 - UBI current revenue model



SOURCE: COMPANY DATA AND BELL POTTER SECURITIES ESTIMATES

New Product Development

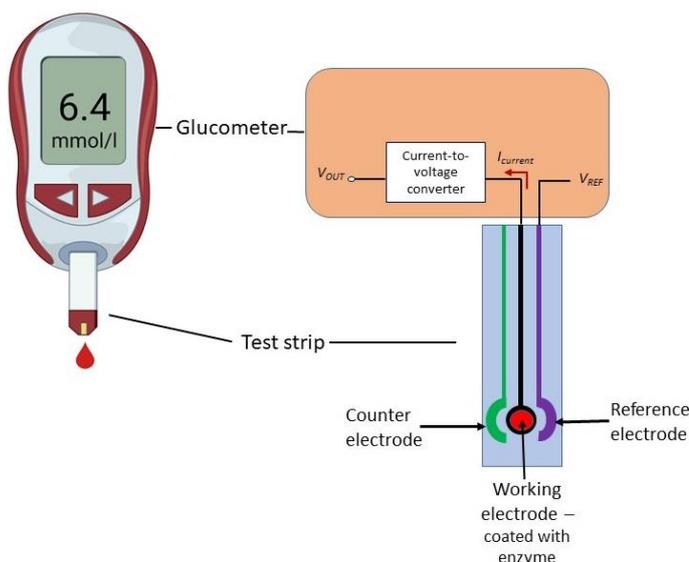
In keeping up with the increasing appetite for point of care and portable testing devices, UBI are currently in the development process for a number of new products aimed at detecting and measuring various circulating proteins, hormones and other analytes.

Much of the UBI marketing material focusses on the company’s detection sensitivity – claiming the detection limits are to be increased up to one billion times. It is unclear whether technology that is capable of detecting molecules in the attomolar ranges have a market, and UBI’s product development in this area is ongoing (although they indicate an investigational COVID test – discussed below – can detect the N-protein of the virus in the femtomolar concentrations). For these reasons, our main focus here is on products and the underlying technologies that have, in our opinion, a current addressable market.

Electrochemical based tests

Most people are familiar with electrochemical based tests via the monitoring of blood glucose using glucometers – a small drop of blood collected from a finger prick is placed on a single-use test strip that has been inserted into a handheld electrochemical meter. The glucose present in the small sample of blood is oxidised in the presence of an enzyme (some devices use glucose oxidase as the enzyme, while others use glucose dehydrogenase attached to a coenzyme, pyrroloquinoline-quinone or flavin adenine dinucleotide) to produce an ionic metabolite (i.e, it is charged) and creates a current that is proportional to the glucose level in the sample. The current then travels to the meter containing a current-to-voltage converter (transducer) to provide a voltage proportional to the level of glucose. This gives a reading either in molar concentration, like we use in Australia (mmol/l) or a mass concentration, like that used in the US (mg/dL). See figure 2.

Figure 2 - Block diagram of traditional blood glucose monitoring tests.



SOURCE: BELL POTTER SECURITIES: IMAGE CREATED USING BIORENDER.COM

These blood glucose monitoring devices are easy to use and affordable, as well as being hugely commercially successful. Yet, limitations in the way electrodes perform using blood samples mean the results are never as accurate at laboratory tests – so if an abnormal reading is detected, a venous drawn sample will be sent off for more sensitive glucose

concentration levels (along with other blood measurements at the discretion of the clinician).

Note that in the schematic image (Figure 2) the electrodes within the cell (on the test strip) are positioned side-by-side or 'co-planar'. This configuration was chosen in the past to minimise electrical interference between the electrodes, but this set-up, in fact, limits the ability to correct for chemical interferences or between-test variations.

Opposing electrode technology

A significant breakthrough developed at Universal Biosensors was the understanding that the interference between electrodes is predictable and can be described mathematically. Surprisingly, this previously discarded "electrical inference" yields additional information about the sample, including information that can correct test-to-test variations depending on the sample type (eg blood, or serum, or even wine – as we will see).

The novel opposing electrode configuration used in Universal Biosensors' platform also removes the limitations that previously prohibited expansion of electrochemical cell technology to the testing of other substances. This new opposing electrode technology forms the basis for expansion by UBI into not only other point of care medical devices, but also other point of use devices in alternative industries. This technology has the following advantages:

- Greater information leading to improved accuracy
- Smaller sample volume requirements
- Low-cost automated manufacturing

Sentia™: wine testing

The first testing device and associated test strips UBI has developed without a partner is the Sentia™ handheld measurement tool. Using the technology described above, the Sentia™ is aimed at the winemaker market – to reduce the cost and time of having wine products tested consistently. Currently, the device can determine concentrations of free sulphur dioxide (SO₂) and malic acid, and UBI is ready to launch glucose capability, and is in the development phase of adding fructose, acetic acid, and total acid to the device by Q4 CY22, early CY23. Concentrations of these molecules affect the quality, taste, preservation, alcohol by volume (ABV), and categorisation of the wines. Most wine makers test only select barrels of a cuvée, and many of the smaller wineries must pay laboratory and transport fees for this process as an external service. Analysis of SO₂, for example, is usually somewhat challenging due to the reactivity of the molecule, and thus usually requires acidification techniques to be used in preparation of the analysis. While it is possible to avoid extensive sample preparation, the cost is often prohibitive for smaller scale wineries. In addition, the handling of the samples is somewhat technical and quality control can often be an issue. For these reasons, very few techniques have been established and accepted by the viticulture community.

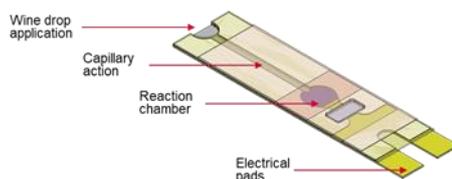
The four most common methods for measuring Free SO₂ are 1) the manual aeration-oxidation (aspiration) technique, which, while highly irreproducible, remains the most widely used method; 2) Ripper Titration, in which iodine and starch are added to the sample. SO₂ in the wine will reduce iodine to iodide and the excess iodine turns the starch a purple colour that can then be compared to a colour chart to indicate SO₂ concentrations. This method is problematic as other compounds including tannins, sugars,

polyphenols amongst others regularly found in wine can also reduce the iodine. 3) The WineScan™ unit produced by FOSS (Denmark). The WineScan™ unit performs a micro-distillation to remove SO₂ from the acidified wine matrix and analyses free SO₂ in the gas phase. Other gases that have dissolved in the wine can interfere with the results and degassing needs to be performed prior to the analysis. Both the degassing and microdistillation are also sources of error. However, while this method seems highly technical and takes up substantial bench space, it is mostly automated and is the most attractive system for larger wineries currently in use. Figure 4 shows the set-up of the WineScan™ unit. 4) The Thermo Scientific™ Gallery™ Discrete Analyzer, a combined photometric and electrochemical analyser that is highly accurate, but is a large, bench-sitting machine that costs upwards of \$500,000.

Enter the Sentia™

The premise of UBI's Sentia™ is that a small drop of wine from every barrel can be tested within seconds by the on-site wine maker who has the device on hand. Unlike the other techniques described above, the Sentia™ is not only small and portable, but also fast (~30 seconds to obtain a reading), and it can analyse more than just free SO₂ (as described above). The device has built-in quality control checks for each test. The Sentia™ test uses UBI's test strip design with two opposing electrodes. The strip contains chemicals that drive a reaction with the free SO₂ contained in the wine that is dropped onto the strip. This reaction (called redox) reduces the SO₂ present to a charged molecule which then generates a voltage along the electrodes that is carried into the Sentia™ device, providing a reading that correlates with the specific concentration of free SO₂ in the wine sample (Figure 3).

Figure 3 - Sentia™ test strip design

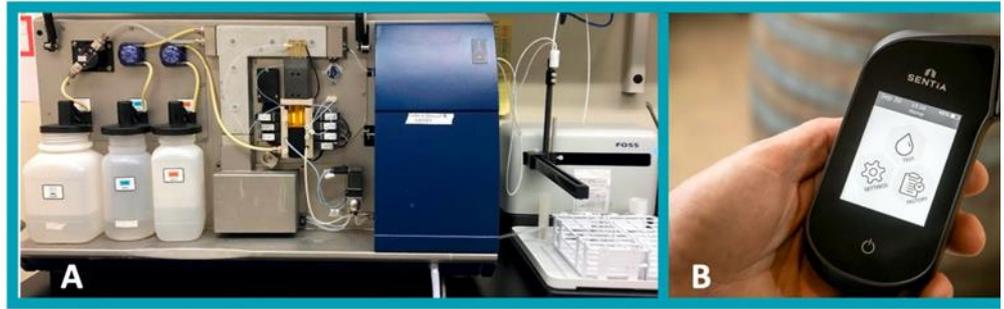


SOURCE: COMPANY DATA

The sensitivity of this device to measure free SO₂ has been compared to the Ripper Titration and the WineScan™ methods by researchers at the Viticulture and Enology Research Centre at California State University Fresno. The authors validated the method and the reliability of the Sentia™ to determine free SO₂ in the wine and concluded that: "The comparison between the Sentia™ analyzer for free SO₂ and two reference methods confirms that the electrochemical analysis in a handheld instrument can provide the same level of accuracy and reliability that could be expected from a standard laboratory method. In addition to that, the compact design and simple procedure eliminate sources of error that can make the analysis of sulfur dioxide extremely challenging."

Another validation study has also been performed by The Australian Wine Research Institute (AWRI - Waite Precinct, Hartley Grove cnr Paratoo Road, Urrbrae, Adelaide) – comparing the performance of the Sentia™ with the most common method: aeration/oxidation, with the results indicating excellent precision and repeatability with the Sentia™ (see Figure 5D).

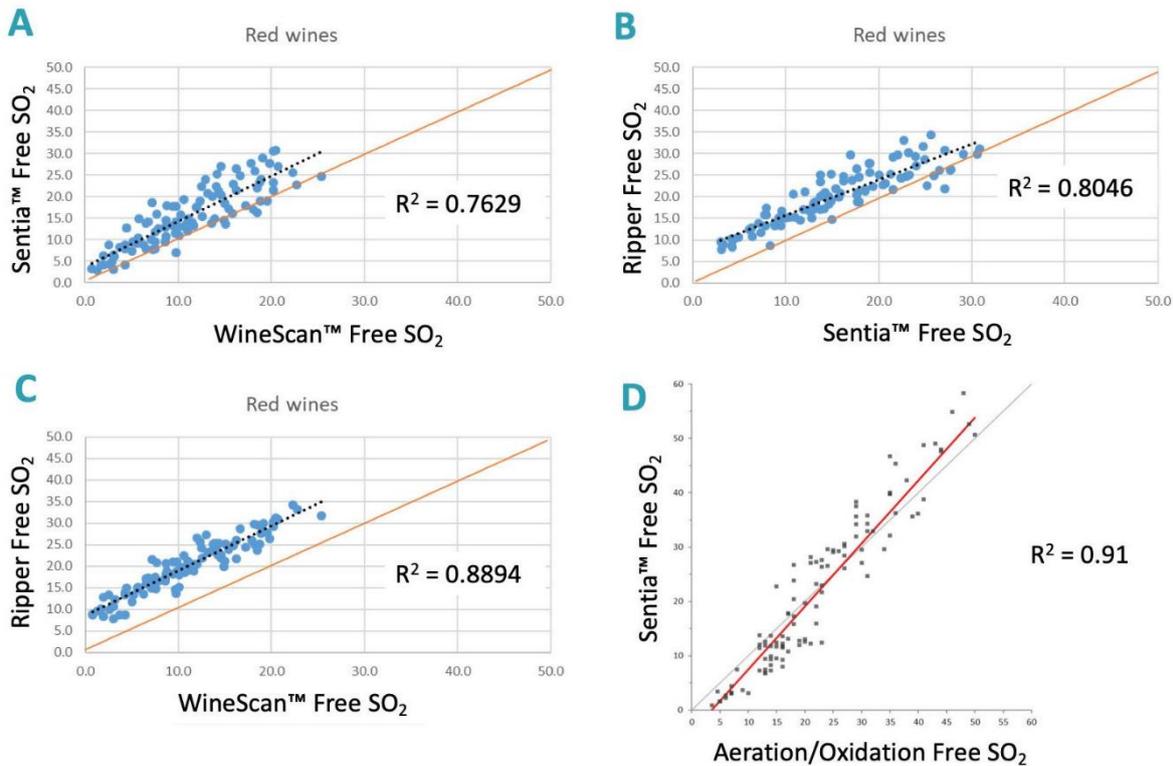
Figure 4 - A) The FOSS FT2 WineScan™ with Free SO₂ module. B) The handheld Sentia™ by Universal Biosensors



SOURCE: COMPANY; AND VITICULTURE AND ENOLOGY RESEARCH CENTRE, UNIVERSITY OF CALIFORNIA FRESNO

Figure 5 shows the comparison of SO₂ readings from 100 red wines between the Sentia™, the Ripper Titration and the WineScan™ methods. R² values indicate how closely aligned the readings for each method is to each other – 1 being perfectly aligned. All methods are suitably close to 1, although splitting hairs may lead to the conclusion that either the Ripper Titration minimally overestimates or that Sentia™ and WineScan™ minimally underestimate. The data comparing the Sentia™ method against the aeration/oxidation method by researchers at AWRI (Figure 5D) indicates that the Sentia™ does not underestimate given the R² value of close to 1 for this comparison.

Figure 5 - Comparison between analytical results for free sulphur dioxide in red wines (n = 100). All values are in mg/L



SOURCE: VITICULTURE AND ENOLOGY RESEARCH CENTRE, UNIVERSITY OF CALIFORNIA FRESNO; AND AWRI, ADELAIDE, SA, AUSTRALIA

Figure 5: A-C) Comparison between analytical results for free sulphur dioxide in red wines (n = 100) between the Sentia™, WineScan™ and Ripper methods. From the Viticulture and Enology Research Centre at California State University Fresno. D) Comparison between analytical results for free sulphur dioxide in wine between the Sentia™ and the aeration/oxidation method. From AWRI. All values are in mg/L.

Market potential for wine testing

UBI released their Sentia™ device in March CY21 and since that time, it has been sold to 9% of Australian production wineries, 5% of those in Canada, and initial sales have occurred in 14 countries. A distribution centre and US subsidiary with a direct sales team have been recently established in Portland the US, and another in The Netherlands.

Fourteen sales and distribution agreements have been signed by UBI and various partners in countries across the globe including Spain and France, most notably Viveley’s have taken the distribution rights for France, have purchased products and have commenced sales. Furthermore, UBI indicate they are in negotiations regarding distribution contracts in another 15+ countries.

Given the uptake of Sentia™ to date, within a one-year period, we conservatively estimate UBI could capture 25-30% of the winemaker market in target countries over the next decade, resulting in the sale of up to 60,000 devices, at a revenue of ~AUD\$100m spread over the next 5 years (see Table 1). Beyond that, ongoing revenue would rely heavily on the purchase of the disposable test strips and any replacement devices. UBI indicate their devices have a 5-year use life.

UBI takes 65% of the profit on the consumable test strips for these devices, with the remaining 35% going to the distributors. This results in a revenue of ~\$2.70 returning to UBI per strip. We estimate a minimum of 3.5 million tests per annum for the two currently available analytes (Free SO₂ and malic acid), if UBI are able to fully penetrate their target markets (see table 1). Thus, we estimate the consumables revenue generated from these tests at up to approximately AUD\$9.5m per annum.

Table 1 - Number of Winemakers in the target regions

Region	Winery Size	Barrels	Number	Free SO ₂ Tests per Winery	Devices per Winery	total # devices
AUS & NZ	Small (<266 Ton)	<665	2,512	130	0.25	628
	Medium (266-4.9k)	665-12250	391	1,000	3	1173
	Large (>5k)	>12500	51	12,000	10	510
US	Small	<665	8,537	130	0.25	2134
	Medium	665-12250	1,396	1,000	3	4188
	Large	>12500	161	12,000	10	1610
ROW	Small	<665	91,000	60	0.1	9100
	Medium	665-12250	7,000	600	3	21000
	Large	>12500	2,000	3,000	10	20000
Total						60343

SOURCE: COMPANY DATA

Xprecia™: PT/INR test - time taken for blood to clot

A prothrombin time (PT) or INR (International Normalized Ratio) test measures how long it takes for the liquid portion of blood to clot in the presence of specific clotting reagents. This liquid portion of the blood is called plasma. Clotting refers to the formation of the blood and proteins into a solid mass – usually to stop bleeding.

The average time it takes for blood to clot is approximately 10 to 14 seconds. If blood clots faster or slower than that, the patient may have a clotting problem. If a doctor suspects this, they may recommend a PT/INR test.

The most common reason for ordering PT/INR tests is to monitor blood levels in patients taking a blood-thinner, like warfarin. Other reasons you may be given an INR test are to:

- Check liver function
- Discover the cause of abnormal bruising or bleeding
- Check for signs of bleeding disorders that can cause bleeding issues, such as haemophilia.

Classic PT/INR tests are performed on blood samples that have been collected from the patient, often sent off to a diagnostic/pathology laboratory and mixed with some predetermined reagents. The samples are then loaded into a large coagulation analyser. These large machines use the photometric principle to monitor changes in the optical density (opacity in the sample) to detect the moment clot formation begins. A typical example of these coagulation analysers is the ACL Top CTS Hemostasis Diagnostics System (there is a family of these machines that differ by age, sample through put and sensitivity). These and other competing machines are generally held by pathology laboratories or large care clinics and are not considered point of care testing. The benefits these large machines offer is that along with testing for PT/INR results, other analytes and metrics from the blood sample can be measured - that are not routine, but are used for investigating blood pathologies (eg, thrombin, antithrombin, homocysteine, plasminogen, plasmin inhibitor and various other proteins and compounds).

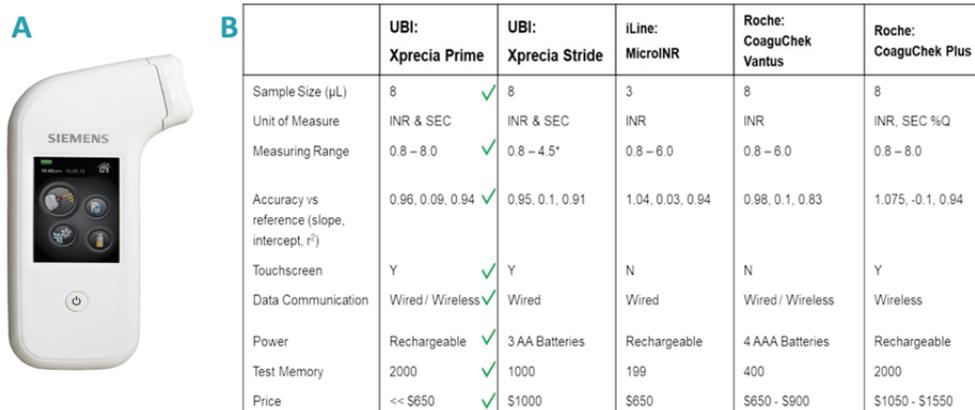
Handheld, point of care devices for the PT/INR test entered the market around 20 years ago. The current available handheld devices include the Roche CoaguCheck® Vantus and CoaguCheck® Plus and the iLine Microsystems MicroINR®; and UBI's Xprecia Stride™ handheld, portable devices that allow for testing of a finger prick of blood (much like the glucose monitors) in the physician's office or by the patient at home (for those devices approved for this use). These are excellent for regular INR monitoring and the data can be collected electronically and sent to the physician if required.

Capillary blood (from the small capillary vessels that create beds of blood supply to the skin – eg in the fingertips) has a disadvantage in that these vessels are very 'leaky', meaning the walls of these vessels often see the water content of the blood squeezed out of the vessel - and this can distort the results because all components of the blood that are not water then become a little more concentrated than what the circulating venous and arterial blood levels are. However, this is only a problem when definitive circulating factors are being investigated say, to diagnose a pathology, and these portable tests remain a good choice for home monitoring, especially given that all tests will be done from capillary blood – meaning the patient and/or physician can still monitor the INR test results against the same sample type each time the test is taken.

The new model: Xprecia Prime™

UBI is currently launching a new, updated version of their Xprecia™ device – the Xprecia Prime™. The table in figure 6B outlines the specifications of all the handheld INR testing devices discussed here. Note that the most comparable product is the Roche CoaguCheck® Plus, and UBI will quite easily undercut this product with Xprecia Prime™ on price.

Figure 6 - A) Xprecia Stride™ and B) comparison table of current handheld INR testing devices



SOURCE: COMPANY DATA

Again, as with Sentia™, both Xprecia™ testing devices use the UBI proprietary two-opposing electrode, gold coated electron transfer system to generate a current once blood encounters reagents present on the disposable strips. A voltage is applied between the two electrodes and the electrons that begin moving create a current. This current is proportional to PT/INR and the device converts this to a readable measurement.

Xprecia™ devices have a barcode scanner for rapid entry of operator ID, patient ID, strip lot #, and calibration entry. UBI indicate their devices have a 5-year use life, and a 1-year warranty (with less than 1% of sales returned under warranty).

Under a previous deal with Siemens, the distribution and marketing of the Xprecia Stride™ was performed by Siemens. A new purchasing arrangement of that deal has seen the transfer of these processes and all sales over to UBI, who will be the sole sponsor of the Xprecia™ systems by May 2023.

CE Mark

At the end of Feb 2022, UBI announced it had been granted the Conformité Européenne (CE) mark for the Xprecia Prime™ – meaning it fully conforms with the European Directives for IVD Medical *In Vitro* Diagnostics and is now approved for sale and distribution throughout Europe. The approval covers all components of the Xprecia Prime™ PT/INR Coagulation system including:

- Xprecia Prime™ coagulation analyzer;
- Xprecia Prime™ PT controls;
- Xprecia Prime™ PT/INR test strips.

Market potential for PT/INR testing

ResearchDive has estimated the global annual coagulation testing market to reach US\$3,566 million by 2026, with a compound annual growth rate of 5.9% when extrapolating from US\$2,241.1 million in 2018 (the last time the actual numbers were calculated). Note that these figures are driven by the enormous growth in Asia (including India).

UBI could potentially take around 20% of the market in Europe and the US, although given the strength of the competition in Roche, we prefer a more conservative forecast of 10-15%. This would result in revenues of approximately AUD\$50million, spread over several years as the devices and the associated consumable test strips are sold. Ongoing revenues may not reach these heights given the 5-year use life of the devices; however, strip purchases would remain strong.

Europe

The Xprecia Stride™ analysers are already being used in 36 countries. Over 3,500 devices have been sold and almost 2 million PT/INR biosensor test strips are manufactured and sold each year by UBI through its global distribution network.

UBI expect to increase the current base of Xprecia™ analysers in Europe with the roll out of the Xprecia Prime™, and accordingly increase the number of test strips sold annually.

USA

UBI require FDA approval to launch the Xprecia Prime™ in the US. In order to fulfil the FDA requirements, UBI have commenced a clinical trial in which just over 160 patients have been enrolled (out of 360 patients). We expect results of this trial to be released in 2HCY22, and if all goes well, FDA approval is expected before the end of 2HCY22.

New product pipeline

Universal Biosensors' manufacturing facility is capable of manufacturing a variety of point of care testing products through all stages of the design and development cycle, then through to high volume commercial production. The current pipeline focusses on three technologies. These are:

1. Petrackr™ blood glucose monitoring for domestic pets
2. Aptamers
3. Lubricin capture technology

Petrackr™: Monitoring blood glucose in our furry friends

With a staggering 463 million humans diagnosed with diabetes mellitus worldwide, 90% of whom have the acquired form: type 2 diabetes, this growing epidemic poses a major burden on individuals and healthcare systems around the globe (International Diabetes Federation – Facts & Figures, 2020). It perhaps, then, is not as surprising as might first

have been thought, that domestic animals (cats and dogs) are also becoming affected by this acquired disease. Afterall, we feed and exercise them. The growing demand for diabetes treatments and monitoring equipment in domestic animals prompted UBI to embark on the development of a specific glucometer, using their electrochemical technology described above, for the measurement of blood glucose levels in domestic animals – the Petrackr™. Petrackr™ is due for commercial launch in Q4 CY22/early CY23.

UBI have indicated the market for this device and related test strips is over AUD\$200m. It is not clear what % of the market UBI may capture.

Aptamer sensors: Honey, I Shrunk the PCR

Much like PCR testing, the aptamer technology uses a small nucleic acid probe to bind very specific molecules in a sample, although, in the aptamer device these are usually proteins, while PCR targets nucleic acid (like RNA or DNA). The sample is often a blood sample but can also be saliva. Unlike PCR, aptamer technology does not require amplification of the target molecule to read the sample concentration. Rather, UBI are using their expertise in electron transfer current generation (this time with 3 electrodes) to create a relative voltage that provides a direct reading of the concentration of the target molecule – almost like a miniature PCR but for protein.

The first aptamer to be validated was the COVID-19 protein aptamer. UBI has indicated a development clinical trial is expected to commence within two months (June 2022), and they are targeting commercial release for late H1CY2023. Whether the market for COVID-19 testing is going to remain strong is of no concern to UBI who have specified the validation of the COVID-19 aptamer as the first of their targets was by chance, and they intend to use the technology for various other tests going forward, including hormones in the female gonadotrophic pathway (estradiol, progesterone, and luteinising hormone) for fertility intervention.

Lubricin coated electrodes

UBI are working on enhancing the detection sensitivity of their electrode system in the test strip by coating the electrode plates with a synthetic version of the protein, lubricin. In the body, lubricin is found in cartilage (along with other organs), and the particular structure of this protein makes it very good at keeping our joints lubricated. It is a flexible, rod-like configuration that allows the protein to bend into a U-shape and hold a fluid layer, as well as repelling any unwanted cell growth or protein adhesion in the clean joint space. All these properties make lubricin an excellent choice to coat the UBI electrodes with, because while the small target analytes are free to pass through the lubricin layer, larger biomolecules that are present in the sample are kept away from the electrodes. This is important because often these larger molecules build-up on the electrodes (biofouling), reducing the sensitivity and reliability of the test (Greene, et al., Adv. Mater. Interfaces 2018, 5, 1701296).

The first test UBI is developing with this lubricin coating technology is for an antigen that is almost exclusively expressed by tumorous cells: Tn antigen. UBI are targeting the oncology market – beginning with either colorectal, prostate or breast cancer, where better diagnostic tests are warranted – for monitoring levels of Tn antigen post remission or after first line treatment failure.

UBI have begun a number of development clinical trials with this test, and we await results over the course of H1CY22.

UBI are actively sourcing partners to further develop and validate these technologies and to add to their development of new tests. As previously discussed, the timelines for these products are beyond the scope of the current valuation.

Partnering

UBI's business model has previously been to commercialise products on its platform technology by partnering with leading healthcare and diagnostic companies including LifeScan (a Johnson & Johnson company) and Siemens Healthcare Diagnostics.

UBI indicate they are continually seeking strategic partnerships with global market leaders as well as engaging in mutually beneficial relationships with other like-minded businesses, universities, and government funded research institutions.

Valuation

The valuation of \$1.25 is derived from a discounted cash flow model. The model includes prospective revenue from future sales of the commercial biosensors (Sentia™ and Xprecia Prime™) and their associated disposable test strips (along with test strips for those customers who have already purchased the Xprecia Stride™ device), and both ongoing and new contracts for services provided by the specialist blood laboratory: The Hemostasis Reference Laboratory (HRL).

We have determined that UBI has the potential to capture approximately 12% of the PT/INR coagulation test device market in Europe and the US; and 25% of the winemaker market in the target regions (see Table 1). Note these wine testing devices are not subject to any regulation.

Upcoming catalysts

- Completion of clinical trial for Xprecia Prime™ in 360 patients expected 2HCY22. We do not foresee any issues given this device is an updated version of the older Xprecia Stride™.
- FDA approval for Xprecia Prime™ is expected before the end of 2HCY22.

Our modelling indicates the company's cash balance dips to AUD\$4.1m by the end of FY23e. We have not assumed any capital raising in our forecasts. The financial model assumes that cash generated from operations in FY24 and beyond will be sufficient to sustain the company's operation.

Table 2 -Cash Balance (A\$m) vs NPAT

A\$m	FY20	FY21	FY22e	FY23e	FY24e
Cash	23.6	15.3	7.2	4.1	8.2
Total assets	56.4	44.5	37.5	36.7	45.9
NPAT	-7.6	-10.5	-7.7	-1.6	7.9

SOURCE: BELL POTTER SECURITIES ESTIMATES

DCF

Our DCF valuation is shown below, along with the calculation of the WACC we have used. The WACC is 11.5% and we have assumed a terminal growth rate of 3%.

Table 3 - DCF for UBI

	FY19	FY20	FY21	FY22e	FY23e	FY24e	FY25e	FY26e	Beyond
Operating cash flow	33.2	-8.3	-9.9	-7.7	-3.1	2.6	10.9	33.2	
Capex	-10.3	-0.4	-0.7	-0.5	-0.5	-0.5	-0.5	-0.5	
Free cash flow	23.0	-8.7	-10.6	-8.2	-3.6	2.1	10.4	32.7	396.8
Present value of cash flows				-7.5	-2.9	1.5	7.0	19.6	212.8
Sum of present values	230.4								
Market value of investments	0.0								
Net debt/(cash)	-7.2								
Equity value (AUD\$m)	223.2								
Equity value per share (A\$)	\$1.25								
WACC calculation									
Risk free rate	4.0%								
Market risk premium	6.0%								
Beta	1.25								
Borrowing rate	5.0%								
Tax rate	30.0%								
Target gearing	0.0%								

Cost of equity	11.5%
Cost of debt	3.5%
WACC	11.500%
Terminal growth rate	3.0%

Source: Bell Potter Securities estimates

Listed Peers

There are a handful of large international companies that are natural competitors for UBI’s point of care (or point of use) devices. These include Roche, bioMérieux SA, BioRad Laboratories, Abbott, Thermo Fisher and Becton, Dickinson and Company. We do not see any benefit in comparing the valuation of UBI with these established, medical device-producing companies.

Table 3 includes a selection of potential peers within the Australian market. These are companies that, like UBI, manufacture diagnostic tests for patients – although each company, including UBI, specialises in a particular sector of the market. Only Rhythm Biosciences does not yet have revenue.

Table 3 - Peer comparisons

	Last	Market Cap	Enterprise Value	FY21 Revenues	FY22 Revenues	FY22 EV/Rev
				Actual	Forecast	
		\$m	\$m	\$m	\$m	
Universal Biosensors	0.81	144	131	5.8	10.8	12.1
Lumos Diagnostics	0.31	46	44	25.1	20.4	2.1
Rhythm Bioscience	1.60	343	337	-	-	-
Atomo Diagnostics	0.12	68	55	6.8	13.5	4.1

SOURCE: BLOOMBERG

Lumos Diagnostics was established in 2015 and merged with RPS diagnostics in 2019. RPS developed a variety of diagnostic tests across multiple indications. The Company’s core competency lies in their proprietary assay development technology for rapid, point-of-care tests. They have three ready for use products and are in early development phases for at least two more.

Rhythm Biosciences is an Australian listed biotech company that is working on a simple and affordable blood test to replace the fecal sample test currently used in screening for the early detection of colorectal cancer. The company was incorporated in June 2017 and are yet to generate revenue although good clinical trial results this year have been released.

Founded in 2010, Atomo Diagnostics is an Australian listed company that develops and manufactures Rapid Diagnostic Test (RDT) platforms that allow for simple point of care testing procedures. Atomo products are currently approved for distribution in over 40 countries.

Financials

Despite the impact of the COVID-19 pandemic, UBI recovered from their FY20 drop in revenue by the end of FY21. Given the uptake of the Sentia™ already (9% of winemakers in Australia and 5% in Canada have already purchased and begun using the device, plus purchases have begun in 14 countries), and the new sales team and distribution centres in the US and The Netherlands, we expect significant positive increases in sales for both the Sentia™ and the Xprecia Prime™ across the next five years (and beyond).

We also expect smaller, although still positive, increases in the revenue generated by the HRL laboratory in Rowville, VIC, particularly as clinical trials continue to get underway post-pandemic.

Table 3 - Revenue from the sale of products and services

	FY20A	FY21A	FY22E	FY23 E	FY24E
Revenue from products	2.6	3.8	7.6	13.7	24.7
Revenue from coagulation testing services	0.6	2.0	2.6	3.8	5.7
Other services	0.1	0.0	0.1	0.2	0.2
Total Services income	0.6	2.0	2.6	3.8	5.7
Total revenue	3.2	5.8	10.2	17.6	30.5
<i>Growth</i>	-54%	80%	76%	72%	73%

SOURCE: COMPANY DATA AND BELL POTTER SECURITIES ESTIMATES

We also expect operating expenses to increase in line with the increased gross sales profit and the ongoing R&D for the new product pipeline. We assume R&D expenses of between AUD\$9 and \$10m for the next 4-5 years. However, the model assumes the company will break through the negative cash flow by FY24, with both NPAT and EBIT in the black by FY24.

Table 4 – Summary income statement

	FY20A	FY21A	FY22E	FY23 E	FY24E
Operating cash flow	-8.3	-9.9	-7.7	-3.1	2.6
Gross profit from sales	0.6	2.1	5.0	9.7	18.3
Operating expenses	-11.0	-15.0	-15.0	-15.5	-16.1
EBIT	-7.6	-10.5	-7.6	-2.0	6.0

SOURCE: COMPANY DATA AND BELL POTTER SECURITIES ESTIMATES

We do not expect UBI to pay a dividend in the foreseeable future.

Their strategic partnering, ongoing R&D and pipeline products all indicate a solid growth pattern for the company. With this substantial growth expected to continue for both product sales and laboratory services, as well as the company's impressive Intellectual Property, we do not expect the company is looking to be acquired at this stage. The current board of directors and senior management are experienced biotech and medical device sector stalwarts who are likely to steer the company through this current growth period, and we expect to see more of their new products and increased profits over the next decade.

Board and Management

Mr Craig Coleman (BCOMM) - NON-EXECUTIVE CHAIRMAN

Mr. Coleman is an experienced investment and funds management executive. His career of 30 years has spanned banking and finance, corporate advisory and funds management. Craig was appointed as non-executive director in June 2016 and has served as Chair of the Remuneration & Nomination Committee since that date. He was appointed as Non-Executive Chairman of the Company on 7th August, 2017.

Craig is currently the Executive Chairman of Viburnam Funds, an Australian-based specialist investment manager founded in 2007 with investments in private and public equities.

During his executive career, Mr. Coleman has held a number of senior executive positions with ANZ Banking Group Ltd, including Managing Director Banking Products, Managing Director Wealth Management, Non-Executive Director E*TRADE Australia Ltd and Head of Retail Banking New Zealand. He was a non-executive director with Bell Financial Group Limited.

Ms Judith Smith (BEC. (HONS), MAPPFIN, F FIN, GAICD) - NON-EXECUTIVE DIRECTOR

Ms. Smith is a highly experienced investment and funds management executive.

Ms. Smith was formerly the Head of Private Equity at IFM Investors, a global fund manager, and Chair of the IFM Risk Committee. Prior to her role at IFM, Ms. Smith held various investment management roles including more than a decade at National Mutual Funds Management Ltd (NMFm). At NMFm, she managed Australian equity research and strategy, as well as Australian equity portfolios.

Mr David Hoey - NON-EXECUTIVE DIRECTOR

Mr. Hoey has more than 25 years' experience in technology financing and commercialization. Mr. Hoey is a US-based director and his primary expertise is in business development, strategic planning, market development, corporate partnering and financings for medical technologies, diagnostics and drug development.

Mr. Hoey has experience as a Chief Executive Officer, director and advisor to various successful biotech companies.

Mr Graham McLean (CIMA AND CPA) - NON-EXECUTIVE DIRECTOR

Mr. McLean has more than 20 years' business and corporate governance experience and is an experienced senior executive leader with extensive service in the medical technology industry in Australia, Asia and US, most recently with Stryker Corporation ('Stryker') as President Asia Pacific from 2017 to 2020.

Mr John Sharman (BECON, CA, MAPPFIN) - CEO

Mr Sharman has extensive international business experience as Managing Director and Chief Executive Officer of ASX-listed companies and private equity businesses operating in Australia, the UK, Europe, Asia and the US. His experience covers the pharmaceutical, medical equipment manufacturing and distribution, finance and FMCG businesses. Before joining Universal Biosensors, Mr. Sharman was the CEO of Medical Developments International (MVP) for over 10 years.

Table 5 - Directors' Status and Interest

Name	Position	Shares
Mr. Craig Evan Coleman	Exec Chairman	220,000
Ms. Judith Ann Smith	NED	300,000
Mr. David L. Hoey	NED	566,414
Mr. Graham A. McLean	NED	0
John Sharman	CEO	306,217
Salesh Balak	CFO	336,558
Total shares held by internal members		1,729,189
Total shares on issues		177,753,504
% shares held by internal		1.0
Free float		99.0

SOURCE: COMPANY

Universal Biosensors (UBI)

COMPANY DESCRIPTION

Universal Biosensors first listed on the ASX in 2006, having been established in 2001. In partnership with LifeScan– a diabetes-focussed company that was a Johnson & Johnson subsidiary at the time, UBI first developed a portable, handheld blood glucose monitor (glucometer): the OneTouch Verio that used the electrochemical cell-based biosensing technology that is now synonymous with UBI. UBI now manufactures products based around a their unique and versatile electrochemical sensor technology, including the Sentia™ wine testing device and the Xprecia™ series (Xprecia Stride™ and now the Xprecia Prime™) for the analysis of blood coagulation. Additionally, they are developing a range of new tests that use their proprietary electrochemical sensing technology. The company is also growing its commercial services laboratory (HRL), via contracts with research partners – mostly those running clinical trials.

KEY RISKS

Key risks we consider to be specific to UBI include, but are not limited to:

Commercial risk: Our forecasts assume revenue growth from both the product sales segment of the business, and from the ability of UBI to continue and to grow contract revenues for its specialty laboratory services business. Failure to achieve growth from either division of the revenue base would could see the company's earnings differ from both our forecasts and the company's forecasts.

Competitive risk: There are a number of companies with tests that operate wine testing services or devices (although none of these are as small, accessible, easy to use or inexpensive as the Sentia™. These may be viewed as competition to UBI in certain instances, especially when winemakers have large volumes (of barrels) and already have either an onsite analyser or a long-standing arrangement with a laboratory service. In our view, however, the Sentia™ leads the field in terms of accuracy, reproducibility, price and ease of use.

Various handheld PT/INR devices are currently on the market (see Figure 6). The most comparable product to the Xprecia Prime™ is the Roche CoaguCheck® Plus, and UBI will quite easily undercut this product with Xprecia Prime™ on price. UBI have already captured part of the market with their first iteration of the device (the Xprecia Stide™) and thus have a suitable track record for marketing and distribution of PT/INR devices. In addition, UBI has set up new distribution centres and associated sales force teams in The Netherlands and now the US.

Clinical and regulatory risk: UBI have commenced a clinical trial for the Xprecia Prime™ to fulfil FDA requirements for approval in the US. 160 patients have been recruited onto the trial thus far (out of a total of 360) and completion is expected mid CY22 – with approval likely to follow in 2HCY22 or early CY23. We do not anticipate any issues given the European CE mark has already been awarded to UBI for this same device. Nevertheless, this is a potential source of regulatory risk for the product.

Funding risk: The company is not yet profitable and yet to generate cash flow from operations. Future profitability is dependent upon successful commercialisation of existing and future products. Shareholders may yet be required to contribute further equity in order to fund the company's operations.

Recommendation structure

Buy: Expect >15% total return on a 12 month view. For stocks regarded as 'Speculative' a return of >30% is expected.

Hold: Expect total return between -5% and 15% on a 12 month view

Sell: Expect <-5% total return on a 12 month view

Speculative Investments are either start-up enterprises with nil or only prospective operations or recently commenced operations with only forecast cash flows, or companies that have commenced operations or have been in operation for some time but have only forecast cash flows and/or a stressed balance sheet.

Such investments may carry an exceptionally high level of capital risk and volatility of returns.

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