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Universal Biosensors (UBI)

Strong first quarter

Speculative

See key risks on Page 5 and Biotechnology Risk Warning on Page 8. Speculative securities may not be suitable for Retail Clients.

Recommendation

Buy (unchanged)

Price

\$0.58

Valuation

\$1.15 (previously \$1.25)

Risk

Speculative

GICS Sector

Pharmaceuticals & Biotechnology

Expected Return

Capital growth	97.5%
Dividend yield	0
Total expected return	97.5%

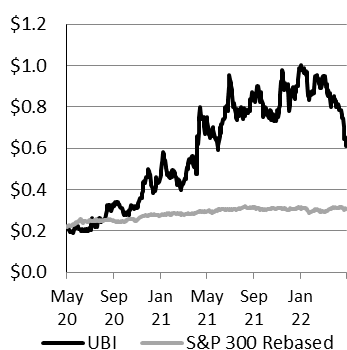
Company Data & Ratios

Enterprise value	\$107.6m
Market cap	\$114.8m
Issued capital	185.5m
Free float	99%
Avg. daily val. (52wk)	\$0.17m
12 month price range	\$0.58-\$1.04

Price Performance

	(1m)	(3m)	(12m)
Price (A\$)	0.84	0.86	0.70
Absolute (%)	-27.38	-28.65	-12.86
Rel market (%)	-25.05	-34.06	-16.82

Absolute Price



SOURCE: IRESS

1Q22 Trading Update

Revenue for UBI was up as expected in this past quarter. The increase was in line with our previous forecast. The company also completed a capital raise for A\$6m. The resulting dilution reduced the valuation by 8% from \$1.25 to \$1.15.

UBI have begun work on upgrading their engineering capabilities to increase their manufacturing of the portable biosensing devices and the new 3-electrode test strips.

The company released interim results from a clinical trial of their new 2- and 3-electrode testing device for patients with colorectal, prostate or breast cancer. The results were highly encouraging, particularly in the colorectal cancer patients, and the UBI portable device seems to outperform current standard of care tests for monitoring of all three cancers. We look forward to further results from this and other trials of the new devices.

136 patients have now been recruited (out of a total 360 required) for a clinical trial of the Xprecia Prime™ portable coagulation test. This trial is a requirement of the FDA approval process. The device is already approved for use in 32 countries in Europe.

Sales and distribution of the Xprecia Prime™ and the Sentia™ wine testing device are likely to continue the upward trajectory following the setup of distribution centres in The Netherlands and in Portland, Oregon (US). The sales teams in both regions also continue to grow.

Investment view: Valuation \$1.15, Retain Buy (Spec.)

We maintain our Buy (Spec.) rating and have reduced our valuation to \$1.15 from \$1.25 per share. The valuation is DCF driven and incorporates modest growth in the uptake and sales of commercial products, and conservative assumptions around increases to the services provided by the company through their specialist haematology laboratory. We observed modest changes (increases) to our forecast revenues, EBIT and NPAT, and the extra cash positively impacted our forecast earnings per share.

Earnings Forecast

December Year End	FY21	FY22e	FY23e	FY24e
Revenues	5.8	10.3	17.7	30.7
EBIT (A\$m)	-10.5	-7.5	-1.8	6.2
NPAT (A\$m)	-10.5	-7.6	-2.0	6.1
EPS (cps)	-5.9	-4.2	-1.1	3.3
EPS growth (%)	nm	nm	nm	nm
PER (x)	nm	nm	nm	17.7
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%	-29%	-8%	20%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Interim results from clinical trial of Tn antigen test.

In April 2022, UBI announced encouraging interim results from a clinical trial of their handheld, portable Tn antigen test.

UBI have been 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. Coating the electrodes contained in the test strips used in UBI's portable devices allows the small target analytes to pass through the lubricin layer, while 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 trial of this technology is testing for Tn antigen in patients with breast, colorectal and prostate cancer. The Peter Mac Development Clinical Trial is run by the Peter Mac Cancer Centre in Melbourne. Tn antigen is almost exclusively expressed by tumorous cells and thus makes for a good target for monitoring of remission and reoccurrence of tumours in these patients. The biosensor itself is designed for delivering easier, cheaper, and more frequent tests than what is currently available.

The trial tests the sensitivity and specificity of UBI's biosensor (both the original 2-electrode disposable strips and a newer model 3-electrode strips) against the current standard care for monitoring tumour status in each of the 3 cancer groups. The "sensitivity" is the true positive rate of detection of the target molecule in cancer subjects, and the "specificity" is the true negative rate in healthy subjects. All results were positive for UBI – particularly their newer 3-electrode device, although these are interim results in a small number of patients.

Results summary tables for colorectal and prostate cancer patients:

Table 1: Tn Antigen test interim results

Colorectal cancer patients:			Prostate cancer patients:		
Cancer (n=16), Healthy (n=10)	Sensitivity (%)	Specificity (%)	Cancer (n=44), Healthy (n=10)	Sensitivity (%)	Specificity (%)
2 Electrode	100	60	2 Electrode	92.9	60
3 Electrode	100	90	3 Electrode	72.7	90
CEA (current standard care)	55.2	83.6	PSA (current standard care)	85.4	30.3

SOURCE: COMPANY DATA

Breast cancer patients:

Data from breast cancer patients was inconclusive with little differentiation between cancer and control subjects likely due to the small sample size (n=6) of cancer patients. UBI state the 3 electrode strips performed better than 2 electrode strips although no data was presented.

UBI are pleased with the interim results and will now invest in a new manufacturing line for the 3 electrode test strips, including an engineering upgrade (work on this has begun). We expect this production line to be ready for manufacturing in ~12 months and to cost ~AUD\$2m.

1Q22 Result

UBI had a good 1Q2022 result with sales up by 10% for products and 15% for services compared to the prior current period (pcp). The services increase was in line with our expectations given this is mostly driven by clinical trials – which have found momentum again post-COVID interruptions. Overall receipts from customers increased by 203% compared to the pcp. This increase was led by:

- the successful launch and sales of the Sentia™ wine testing product in 2021 for sulphur dioxide, to which malic acid was added in Q12022;
- Deferred revenue from UBI’s prior obligation to transfer Xprecia Stride™ strips to Siemens (received in 2019) was fully utilised in 2021; and
- Finally, revenue from coagulation testing increased by 15% as a result of new contracts and more customers, all of which was helped by the completion of distribution centre set-ups and hiring of associated sales forces in both The Netherlands and the US (Oregon).

Not surprisingly, the R&D spend for the quarter was up at A\$3.6m, representing an increase of A\$2.2m compared to pcp. UBI invested A\$1.7m in the development of the veterinarian blood glucose product and a further A\$0.2m on a clinical trial for Xprecia Prime that is required by the FDA in the USA. Remaining R&D spend was used for testing and development of UBIs oncology, fertility and COVID biosensors.

Share placement effects

UBI raised A\$6m and issued 7.8 million shares (CDIs) via an institutional placement in April 2022. This capital raise and associated increase in shares on issue has had a material effect on our forecasts as follows:

Cash increased from FY22e onwards

Cash + Restricted cash (A\$m)	FY20	FY21	FY22e	FY23e	FY24e
New	28.1	18.1	16.0	12.6	14.8
Old	28.1	18.1	9.9	6.4	8.5
% Change	0.0%	0.0%	61.6%	96.9%	74.1%

SOURCE: COMPANY DATA AND BELL POTTER SECURITIES ESTIMATES

Note that UBI intends to raise a further A\$20 million via a fully underwritten 1 for 6.85 non-renounceable pro rata entitlement offer of CHESS depository interests over new UBI ordinary shares (New CDIs) to eligible retail and institutional security holders at an offer price of A\$0.77 per New CDI. We will update our forecasts at completion of this entitlement offer (20 May 2022).

Valuation

FY22 forecasts modestly shifted following placement and 1Q results

The activities described above have impacted our forecasts and valuation modestly, resulting in a new valuation of A\$1.15 (from A\$1.25), with no change to our strong Buy recommendation.

The cash raised during this 1Q2022 has improved the company's cash balance as described above, and 7.8 million new shares were issued. We observed modest changes (increases) to our forecast revenues, EBIT and NPAT, and the extra cash positively impacted our forecast earnings per share (see table 3).

Our valuation is derived from a discounted cash flow model. The WACC is 11.5% and we have assumed a terminal growth rate of 3%.

Table 3 - Key changes to our forecasts

	FY22e			FY23e		
	New	Old	% Change	New	Old	% Change
Revenues	10.3	10.2	1.0%	17.7	17.6	0.6%
EBIT	-7.5	-7.6	-1.3%	-1.8	-2.0	-10.0%
NPAT	-7.8	-7.7	0.8%	-2.0	-2.1	-4.8%
EPS (cps)	-4.2	-4.3	2.3%	-1.1	-1.2	8.3%

SOURCE: COMPANY DATA AND BELL POTTER SECURITIES ESTIMATES

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.

Table 4- Financial summary

A\$m	FY20	FY21	FY22e	FY23e	FY24e	Valuation Ratios (A\$m)	FY20	FY21	FY22e	FY23e	FY24e
Year Ending 30 June						Reported EPS (cps)	-4.3	-5.9	-4.2	-1.1	3.3
Revenue	3.2	5.8	10.3	17.7	30.7	Normalised EPS (cps)	-4.3	-5.9	-4.2	-1.1	3.3
Change	-54%	80%	40%	53%	55%	EPS growth (%)	nm	nm	nm	nm	nm
	0.0	0.0	0.0	0.0	0.0						
Cost of sales	-2.6	-3.7	-5.1	-7.8	-12.2	PE(x)	nm	nm	nm	nm	17.7
Gross profit	0.6	2.1	5.1	9.9	18.5	EV/EBIT (x)	nm	nm	nm	nm	nm
Gross margin	19%	36%	50%	56%	60%						
	0.0	0.0	0.0	0.0	0.0	Total assets	56.4	44.5	43.6	42.4	49.9
Other income/(expense)	4.9	4.5	4.5	6.0	6.0	Net Assets	38.0	27.6	26.0	24.1	30.2
Expenses (excl. D&A, Int.)	-11.0	-15.0	-15.0	-15.5	-16.1	NTA	23.7	15.0	15.5	15.8	24.0
% of revenue	-342%	-259%	-146%	-88%	-53%	NTA/share cps	0.1	0.1	0.1	0.1	0.1
	0.0	0.0	0.0	0.0	0.0	Book value per share	0.0	0.0	0.0	0.0	0.0
EBITDA	-5.4	-8.3	-5.3	0.3	8.4						
Depreciation and amortisation	-2.2	-2.2	-2.2	-2.2	-2.2	P/NTA (x)	434.8	689.3	692.6	682.0	447.5
EBIT	-7.6	-10.5	-7.5	-1.8	6.2	Book Value Per Share (cps)	0.2	0.2	0.1	0.1	0.2
Net interest (expense)/revenue	0.0	0.0	-0.1	-0.1	-0.1	Price/Book (x)	271.3	373.4	413.7	447.4	355.8
Pre-tax profit	-7.6	-10.5	-7.6	-2.0	6.1						
Income tax expense	0.0	0.0	0.0	0.0	0.0	DPS (cps)	0.0	0.0	0.0	0.0	0.0
NPAT	-7.6	-10.5	-7.6	-2.0	6.1	Payout ratio %	0.0	0.0	0.0	0.0	0.0
						Dividend Yield %	0.0	0.0	0.0	0.0	0.0
						Franking %	0.0	0.0	0.0	0.0	0.0
Cashflow (A\$m)	FY20	FY21	FY22e	FY23e	FY24e	FCF yield %	nm	nm	nm	nm	nm
Net loss	-7.6	-10.5	-7.6	-2.0	6.1						
D&A and other non cash items	3.0	2.1	2.2	2.2	2.2	Net debt/(Cash)	-23.5	-15.3	-13.2	-9.7	-12.0
Change in working capital	-3.6	-1.5	-2.2	-3.1	-5.5	Net debt/Equity %	0%	0%	0%	0%	0%
Operating cash flow	-8.3	-9.9	-7.6	-2.9	2.8	Net debt/Assets %	0%	0%	0%	0%	0%
Proceeds from sale of PPE	0.0	0.0	0.0	0.0	0.0	Gearing %	0%	6%	6%	6%	6%
Purchases of PPE	-0.4	-0.7	-0.5	-0.5	-0.5	Net debt/EBITDA (x)	Net Cash	Net Cash	Net Cash	Net Cash	Net Cash
Proceeds from gov grants and insurance	0.0	0.0	0.0	0.0	0.0	Interest cover (x)	na	na	na	na	na
Acquisition of assets	0.0	0.0	0.0	0.0	0.0						
Investing cash flow	-0.4	-0.7	-0.5	-0.5	-0.5	ROE %	-20%	-38%	-29%	-8%	20%
Repayment/proceeds of borrowings	0.0	0.0	0.0	0.0	0.0						
Borrowing costs	0.0	0.0	0.0	0.0	0.0						
Proceeds from stock options exercised	0.0	0.1	0.0	0.0	0.0						
Financing cash flow	0.0	0.1	6.0	0.0	0.0						
Net change in cash	-8.6	-10.5	-2.1	-3.4	2.3						
Cash at start of period	37.2	28.1	18.1	16.0	12.6	Segmentals (A\$m)	FY20	FY21	FY22e	FY23e	FY24e
Exchange rate impact	-0.5	0.5	0.0	0.0	0.0	Revenue					
Cash at end of period	28.1	18.1	16.0	12.6	14.8	Sale of Goods	2.6	3.8	7.6	13.7	24.7
						Services Income	0.6	2.0	2.6	4.0	6.0
						Total revenue	3.2	5.8	10.3	17.7	30.7
						Growth					
						Sales of goods	-47%	49%	100%	80%	80%
						Services income	-69%	208%	35%	50%	50%
						Total growth	-54%	80%	40%	53%	55%
Balance Sheet (A\$m)	FY20	FY21	FY22e	FY23e	FY24e	Interim Results	1H21	2H21	1H22e	2H22e	
Cash & restricted cash	28.1	18.1	16.0	12.6	14.8	Revenues	3.4	2.4	4.6	5.6	
Inventories	1.9	2.1	4.9	8.5	14.7	EBIT	-2.6	-7.9	-3.4	-4.2	
Accounts receivable	0.1	0.5	0.5	0.9	1.6	NPAT	-2.6	-7.9	-3.5	-4.2	
PPE	4.4	4.1	4.6	5.1	5.6						
Intangibles	14.3	12.7	10.5	8.3	6.1						
Right-of-use assets	4.0	2.1	2.1	2.1	2.1						
Other assets	8.2	7.8	7.8	7.8	7.8						
Total assets	56.4	44.5	43.6	42.4	49.9						
Accounts payable	0.4	0.4	1.1	1.9	3.3						
Accrued expenses	1.2	2.8	2.8	2.8	2.8						
Contingent consideration	1.9	2.1	2.1	2.1	2.1						
Current Lease liabilities	0.5	0.5	0.5	0.5	0.5						
Asset retirement obligations	2.7	2.7	2.7	2.7	2.7						
Lease liabilities	3.6	1.7	1.7	1.7	1.7						
Other Liabilities	8.0	6.7	6.7	6.7	6.7						
Total liabilities	18.4	16.9	17.6	18.4	19.8						
Net Assets	38.0	27.6	26.0	24.1	30.2						
Share capital	93.6	93.7	93.7	93.7	93.7						
Accumulated deficit	-47.7	-55.3	-55.3	-55.3	-55.3						
Current year losses	-7.9	-10.8	-18.4	-20.4	-14.2						
Total shareholders' equity	38.0	27.6	26.0	24.1	30.2						

SOURCE: BELL POTTER SECURITIES ESTIMATES

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

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The fact that the intellectual property base of a typical biotechnology company lies in science not generally regarded as accessible to the layman adds further to the riskiness with which biotechnology investments ought to be regarded. Clinical and regulatory risks are inherent in biotechnology stocks. Biotechnology developers usually seek U.S. FDA approval for their technology which is a long and arduous three phase process to prove the safety, effectiveness and appropriate application or use of the developed drug and even after approval a drug can be the subject of an FDA investigation of subsequently discovered possible links between the drug and other diseases not previously diagnosed. Furthermore, the Australian exchange listed biotechnology sector is subject to influence by the global biotechnology sector, particularly that in the USA. Consequently, Australian exchange listed biotechnology stocks can experience sharp movements, both upwards and downwards, in both valuations and share prices, as a result of a re-rating of the sector both globally and in the USA, in particular. Investors are advised to be cognisant of these risks before buying such a stock.

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