

Universal Biosensors Inc

Market update

 Placing the universal power of biosensors into the hands of those who need it

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Placing the universal power of biosensors into the hands of those who need it

Universal Biosensors Inc

UBI

UBI is a biosensor company and **world leader** in electrochemical cell technology.

New technology has expanded our detection limits **by 1 Billion (1,000,000,000)** times.

UBI's biosensor technology platform has been used to deliver more than **10 billion diagnostic tests** to patients worldwide generating billions of dollars in sales.

Our patented technology is based on diagnosis and measurements using a portable handheld device from a "**finger prick of blood**" sample (size).

Our ambition is to build a multi product stable of biosensors in large markets which generate ongoing revenue streams.

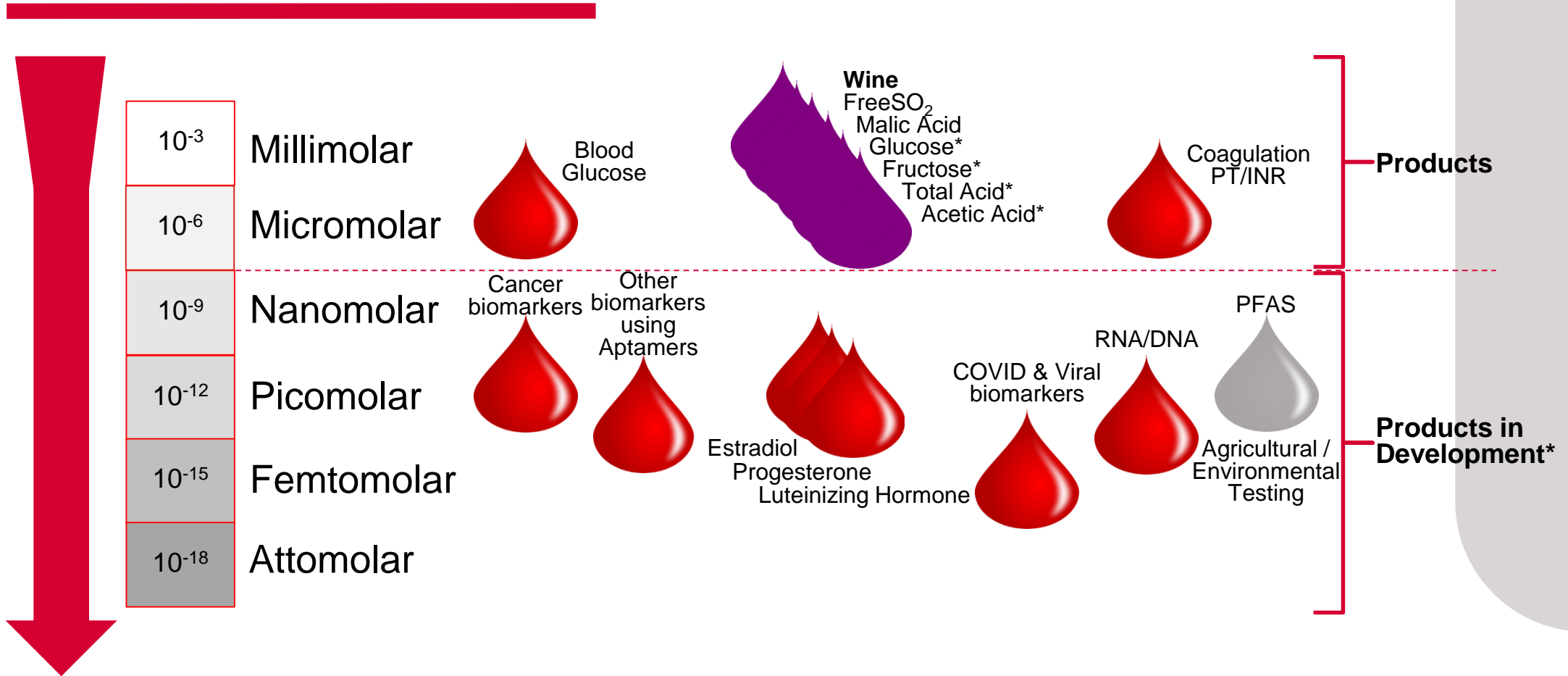
Our revenue model is to sell the handheld, portable analyzer into high volume repeat-use scenarios and then sell single use, disposable biosensor strips which are used for each diagnostic test.

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New Technology

Detection Limits Increased by ≈ 1 Billion Times

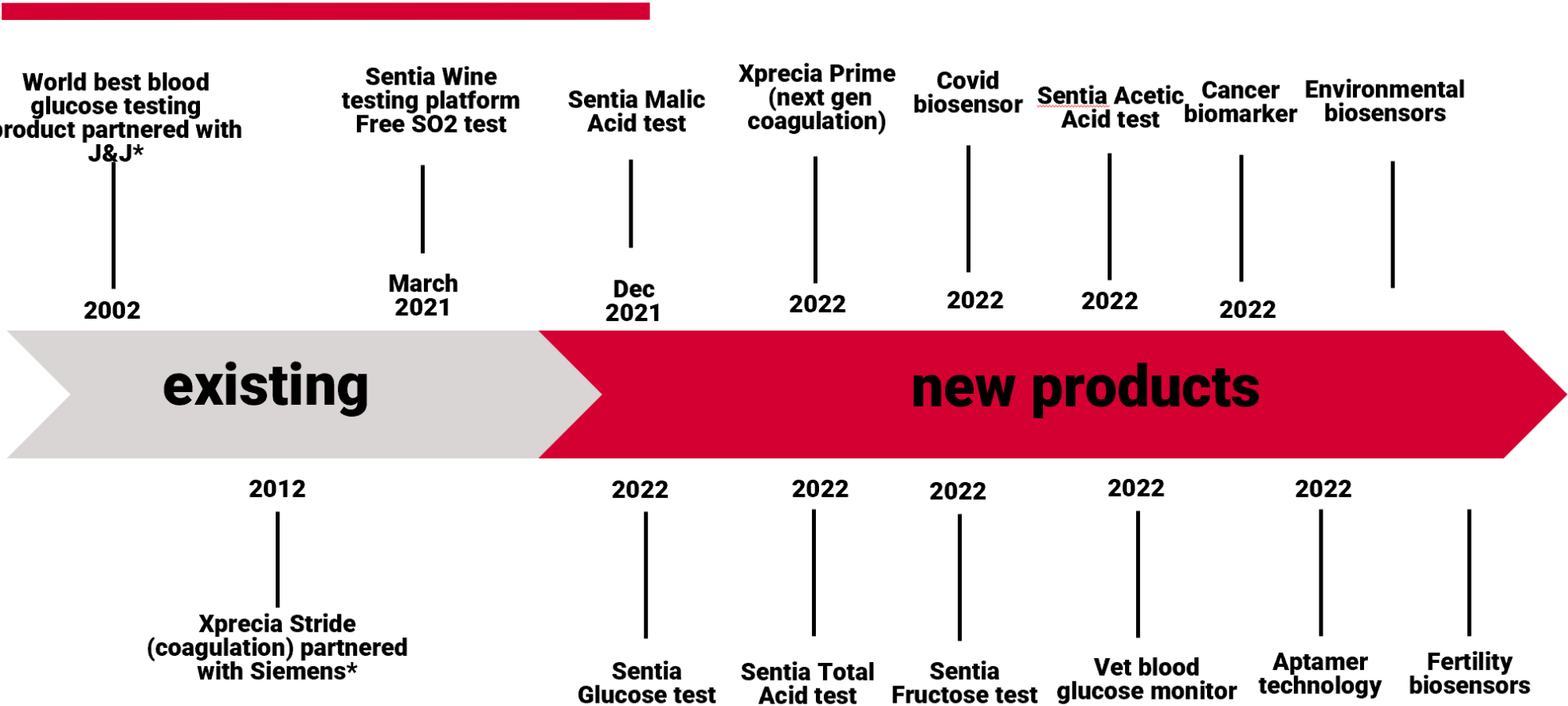


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New Technology

Products and Timelines



*J&J and Siemens contracts and partnerships have ended with no further revenues or expenditure expected.

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Sentia™

Update

Sentia™ is a hand-held, portable testing device which will **change the nature of laboratory testing** in the wine industry.

Two products launched so far: **Free SO2 and Malic Acid tests.**

Glucose test ready for launch.

Fructose test delayed.

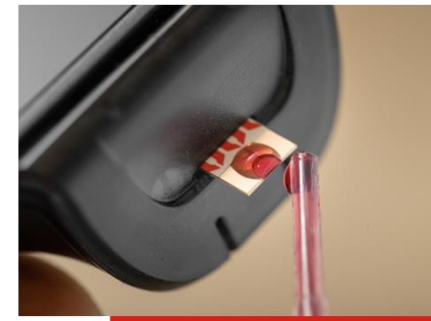
Sentia delivers **significant cost savings** and productivity gains to the global wine industry.



01. Easy-to-follow prompts



02. At-barrel convenience



03. Only small sample drop required



04. 30 second result

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Sentia™

Testimonial from USA

Carol Shelton is widely cited as **the most awarded winemaker in the U.S.** She has won countless medals for her wines over her 45 years in the industry and has been honored as Winemaker of the Year numerous times. Her wines have been selected for the Wine Spectator's annual "Top 100 Wines of the World" honour a total of 4 times in the past 7 years.

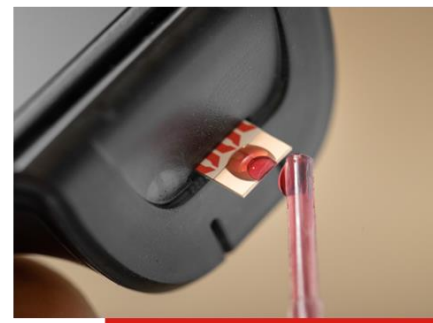
"The Sentia free SO2 measurement tool has been a boon to a small winery like us which does not have a full lab. We can get immediate results at lower costs than outside labs.....it was a no-brainer purchase that is going to improve our wine quality by allowing for more frequent testing and thus better SO2 protection of my wines."



01. Easy-to-follow prompts



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04. 30 second result

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Sentia™

Update

UBI launched “**Sentia Wine Analyzer**” in March 2021.

- 9% of production wineries in Australia have purchased Sentia.
- 5% of production wineries in Canada purchased Sentia.
- 14 Distribution deals done globally.
- First sales made in 14 countries.
- Direct sales force established in USA (January 2022).
- Distribution centre and USA subsidiary established.
- Good progress being made in Europe.
- Negotiating distribution contracts in *Italy, Austria, Germany, Hungary, Serbia, Poland, Bulgaria, Romania, England, Argentina, Chile, Turkey, USA.*

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World Wide Market				
Number of tests per year				
	ANZ	USA	RoW	Total
Free SO ₂	1,329,560	4,433,985	15,660,000	21,423,545
Malic Acid	930,692	3,103,789	10,962,000	14,996,481
Glucose & Fructose	2,127,296	7,094,376	25,056,000	34,277,672
Total Acid	664,780	2,216,992	7,830,000	10,711,772
Acetic Acid	1,329,560	4,433,985	15,660,000	21,423,545
Total Tests	6,381,888	21,283,127	75,168,000	102,833,015
Total Devices	2,311	7,929	50,100	60,340

World Wide Market				
Estimate global value (AUD)				
	ANZ	USA	RoW	Total
FSO ₂	4,653,460	22,169,923	78,300,000	105,123,383
Malic Acid	7,445,536	35,471,876	125,280,000	168,197,412
Glucose & Fructose	7,445,536	35,471,876	125,280,000	168,197,412
Total Acid	3,988,680	13,301,952	46,980,000	64,270,632
Acetic Acid	10,636,480	35,471,880	125,280,000	171,388,360
Total Tests	34,169,692	141,887,507	501,120,000	677,177,199
Total Devices	4,044,250	25,485,906	139,564,286	169,094,442
Total Revenue	38,213,942	167,373,413	640,684,286	846,271,641

All calculations are estimated and Australian dollars

Source: Australian and New Zealand Wine Industry Directory, New Zealand Winegrowers Annual Report, OIV Statistical Report on World Vitiviniculture, UBI Winemaker Interviews



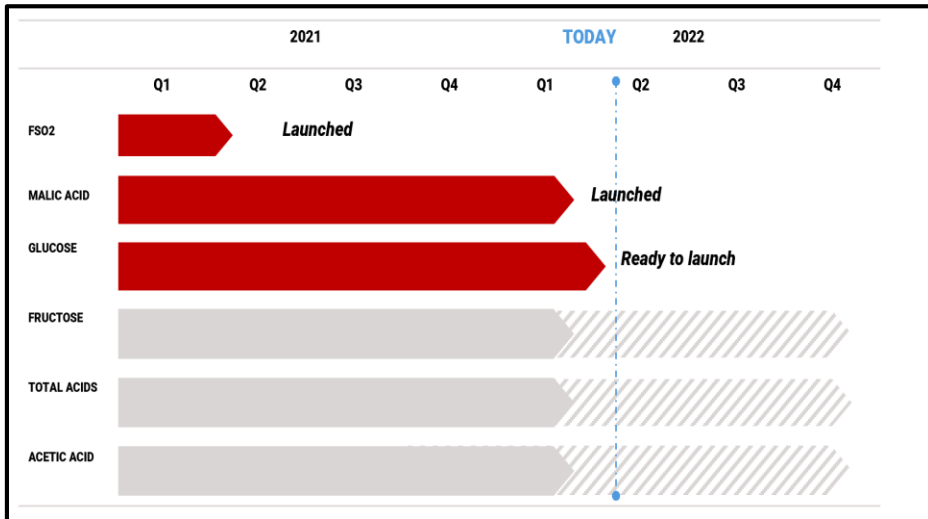
Sentia™

New Products and Market Potential

All winemakers test and monitor

- Free SO2 for every wine they make.
- Malic Acid for every wine they make.
- Total Sugars (Glucose & Fructose) for 99% of wine they make.
- Total Acid for 99% of wine they make.
- Acetic Acid for 90% of wine they make.

Target Dates for New Product Launch



UBI estimate of potential global market share	Potential UBI Sales (\$AUD)
5%	24,121,822
10%	44,071,660
15%	64,021,499
20%	83,971,337
25%	106,243,182

Assumptions

UBI has used its own market information and assumptions to estimate potential sales based on share of global market

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Xprecia Prime™

Approved for Sale by European Regulatory Authorities

Xprecia Prime received approval from European regulators on 24 February 2022.

The approval means Xprecia Prime can be sold in 32 countries across Europe.

UBI expect the first 1,000 Xprecia Prime systems to be delivered H1 22.

UBI has spent 7 years and tens of millions of dollars developing Xprecia Prime.

UBI believe Xprecia Prime's performance is equal to or better than any PT/INR device available.

	UBI: Xprecia Prime	UBI: Xprecia Stride	iLine: MicroINR	Roche: CoaguChek Vantus	Roche: CoaguChek Plus
Sample Size (µL)	8 ✓	8	3	8	8
Unit of Measure	INR & SEC	INR & SEC	INR	INR	INR, SEC %Q
Measuring Range	0.8 – 8.0 ✓	0.8 – 4.5*	0.8 – 6.0	0.8 – 6.0	0.8 – 8.0
Accuracy vs reference (slope, intercept, r ²)	0.96, 0.09, 0.94 ✓	0.95, 0.1, 0.91	1.04, 0.03, 0.94	0.98, 0.1, 0.83	1.075, -0.1, 0.94
Touchscreen	Y ✓	Y	N	N	Y
Data Communication	Wired / Wireless ✓	Wired	Wired	Wired / Wireless	Wireless
Power	Rechargeable ✓	3 AA Batteries	Rechargeable	4 AAA Batteries	Rechargeable
Test Memory	2000 ✓	1000	199	400	2000
Price	<< \$650 ✓	\$1000	\$650	\$650 - \$900	\$1050 - \$1550

*4.5 in USA, 8.0 in EU.
Xprecia Prime 8.0 in EU. TBC in USA
All prices are Australian dollars
Source: iLine, Roche

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Xprecia Prime™

Approved for Sale by European Regulatory Authorities

Clinical trial required for FDA approval **commenced** and first patient enrolled

- 63 of 360 patients recruited.
- Clinical trial expected to be **completed mid 2022**.

Regulatory submission then **approval** expected in **USA H2 2022** or Q1 2023.

Direct sales staff have been employed in Europe to facilitate growth.

Distribution centre and European subsidiary established.

UBI expect to increase its market share of the global PT/INR coagulation market with the launch of Xprecia Prime.

UBI estimate of potential global market share	Potential UBI Sales (\$AUD)
5%	21,296,773
10%	42,593,546
15%	63,890,319
20%	85,187,092
25%	106,483,865

Assumptions and References

UBI has used its own historical market information and public data to generate estimated potential sales based on share of global market. Sources include Greystone Research, Global Data, Siemens, Boston Biomedical Analysis and Lincare.

Xprecia Stride™

Sold in 36 Countries

Contribution from Gross Margin **up 17%** during FY21.

Average Selling price per strip **up 27%** during FY21.

Agreed **16 new distribution deals**.

Installed base of over 3,500 units worldwide.

50+ distributors (x Japan) worldwide and **sold in 36 countries**.

Migrating existing Siemens distribution network to UBI.

Strong sales growth expected Q1 FY22.

New distribution deals in

- ✓ *Germany*
- ✓ *Austria*
- ✓ *Albania*
- ✓ *Spain*
- ✓ *Chile*
- ✓ *Czech Republic*
- ✓ *Switzerland*
- ✓ *Poland*
- ✓ *Malaysia*
- ✓ *Romania*
- ✓ *Slovenia*
- ✓ *Serbia*
- ✓ *Malta*
- ✓ *Kosovo*
- ✓ *Cyprus*
- ✓ *Macedonia*

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Specialist Blood Laboratory

Hemostasis Reference Laboratory

Our specialist blood laboratory business **grew sales by 245%** during FY21.

We are expanding our specialist services into:

- Inflammatory disease;
- Cytokines; and
- Multiplex Immunoassay Platform.

New clients have been secured.

New equipment has been purchased.

New premises and laboratory fitted out.

Good longer term sales growth prospects.

New Product Development

The Future of UBI

In addition to the Sentia wine tests in development (Fructose, Total Acid and Acetic Acid) and Xprecia Prime (UBI's new PT/INR coagulation testing platform); **UBI is developing** a suite of new products all of which use UBI's handheld, portable analyzer, including:

Diabetes test for animals.

Tn Antigen cancer biosensor

A cancer biomarker capable of detecting changes of a patient's cancer status (carcinoma) from a finger prick of blood.

Aptamer based biosensors. UBI's first two products in development using aptamers are:

1. An instant SARS-CoV-2 N-Protein (COVID-19) test capable of detecting and measuring a patient's COVID-19 status within 30 seconds from a drop of saliva or nasal swab
2. Three instant fertility hormone tests (Estradiol, Progesterone and Luteinizing Hormone).

New Product Development

Petrackr™ Blood Glucose Monitor

Biosensor test strip and meter development for measuring and monitoring of blood glucose for diabetes in cats and dogs has commenced and is on track.

Anticipated to launch Q4 2022 (early 2023).

There are no significant regulatory hurdles.

Market opportunity in excess of \$200m.

UBI estimate of potential global market share	Potential UBI Sales (\$AUD)
5%	9,621,294
10%	21,426,622
15%	35,787,816
20%	59,163,570
25%	82,348,294

Assumptions

UBI has used its market information and public data to generate estimated potential sales based on share of global market.

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New Product Development

Tn Antigen Cancer Biomarker

UBI's ambition is:

- To develop a finger prick blood test which can be used by oncologists in clinics, hospitals, GP clinics or at home.
- For the handheld Tn biosensor to accurately measure a patient's cancer status (monitoring of remission and reoccurrence) in easier, cheaper and more frequent tests.
- Ultimately the Tn cancer biomarker test may be used for cancer screening and staging.

New Product Development

Tn Antigen Cancer Biomarker

Tn antigen is almost exclusively associated with the development and progression of cancer (carcinoma's).

Tn antigen is an O-glycan that is very rarely expressed in healthy blood cells or peripheral tissues^[1].

Tn antigen may be used:

- To monitor the State of Cancer Remission^[2,3,4]
- To measure the Aggressiveness and Progression of Cancer^[1,2,3,5,6,7,8,9,10,11]
- To measure the Effectiveness of Cancer Treatment^[2,3,11]
- As a biomarker for Early Detection of Cancer^[1,5,6,12,13]
- In Research and Development markets^[13]

New Product Development

Tn Antigen Cancer Biomarker

Tn Antigen biosensor development work progressing well.

The 338 patient Development Clinical Study is “on track, on budget and on time” and is due for completion in April 2022. Development Clinical Study Trial results are expected shortly after.

Trials being conducted with Peter MacCallum Cancer Centre, Victorian Cancer Biobank and CIC bioGUNE in Spain.

The aim is each patient blood sample will be used to:

- Determine the clinically relevant range of Tn concentrations;
- Confirm the role of Tn antigen in multiple cancer types;
- Validate the performance of UBI’s handheld point-of-care device & test strip;
- Determine the sensitivity and specificity of the Tn Antigen biosensor; and
- Benchmark the performance of the Tn Biosensor against existing biomarker performance.

New Product Development

Aptamers Based Biosensors

UBI has proven in its feasibility work that aptamers (very specific functional and targeted tests for analytes of interest) can be laid down onto our biosensor strips and specific targets can be detected and measured from a very small sample size delivering almost instant results.

Aptamers

- are synthetically made molecules structured as single-stranded DNA or RNA oligonucleotides.
- can be designed to mimic the functional properties of monoclonal antibodies.
- bind to very specific target molecules with high affinity and specificity (picomolar detection limits or better).
- are an alternative to therapeutic antibodies or peptide ligands.

UBI believes that aptamer sensing on its portable handheld device represents the future of detection, diagnosis and monitoring of many disease states.

Most specifically, UBI is working on two new products using the aptamer-based sensing platform:

1. Saliva or nasal based test that can instantly detect SARS-CoV-2 N-Protein (COVID-19).
2. Fertility hormones (Estradiol, Progesterone and Luteinizing Hormone) to be used in IVF and advance fertility treatments.

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New Product Development

COVID-19

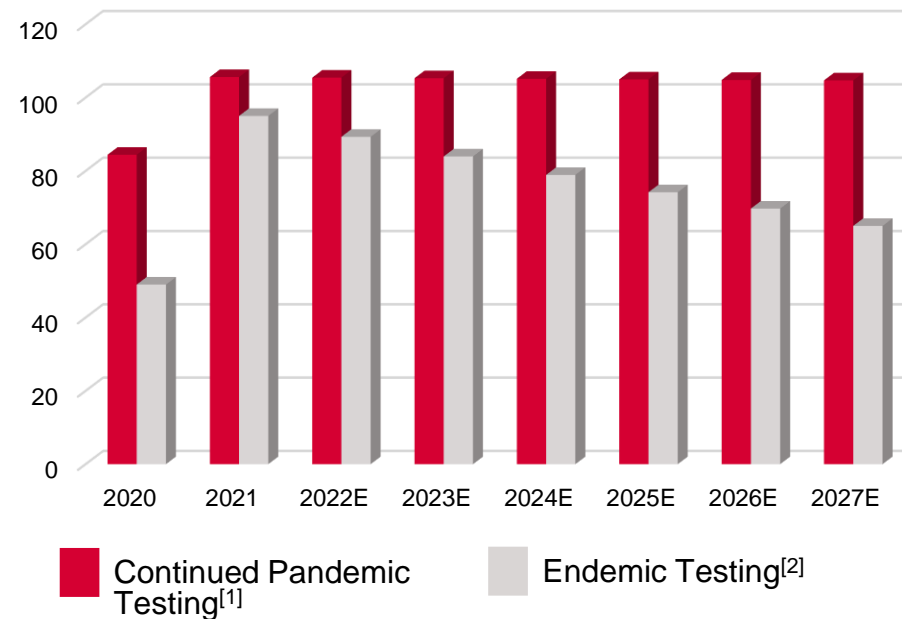
UBI has secured a global exclusive License for the commercialisation of a SARS-CoV-2 N-Protein detection test (COVID -19).

UBI has successfully completed its feasibility program and performed tests on hundreds of “spiked N-Protein samples”.

UBI is preparing for live virus and human trials as follows:

- Spiking saliva study to confirm performance at different concentrations of virus.
- Live virus across the different COVID-19 variants in saliva and nasal swab samples to test
 - ✓ Reproducibility,
 - ✓ Clinical sensitivity,
 - ✓ Clinical specificity, and
 - ✓ Limit of detection.

COVID-19 Testing Market (Billion USD)



[1] Grandview Research
[2] Research Dive

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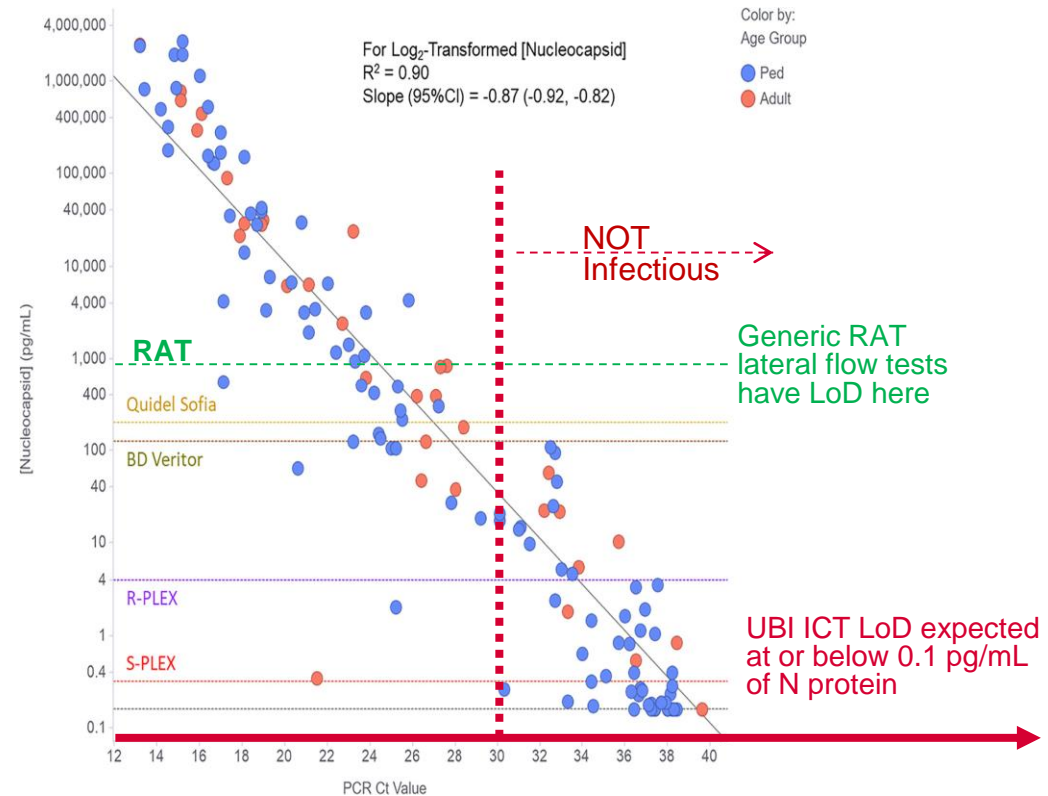
New Product Development

COVID-19

If successful, the development of UBI's Instant COVID Test (ICT) could:

- Deliver PCR levels of detection and accuracy.
- Provide near instant responses using UBI handheld portable device.
- Provide flexibility for mass testing.
- Collate and manage “meta data” from patients testing for COVID-19.
- Should be able to detect future COVID variants as N-Protein noted to be conserved.

Limits of Detection (LoD) Comparison



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New Product Development

Fertility Biosensors

UBI is developing an **aptamer based** handheld device and consumable biosensor test strip that (if successful) will be able to detect key fertility hormones (Estradiol, Progesterone and Luteinizing Hormone) in small samples of whole blood in less than 5 minutes.

Patients would be able to self test and monitor in the privacy of their own home.

Future applications include HCG, AMH, FSH etc.

Delivery of aptamers commissioned and expected H1 2022.

Proof of concept, feasibility and development trials to commence Q2 2022.

Region	Number of Cycles	Testing Market (\$AUD)
Asia	1,025,917 ^[1,2]	553,995,180
Europe	918,159 ^[3]	495,805,860
North America	347,625 ^[4,5]	187,717,500
Latin America	93,600 ^[6]	50,544,000
AUS & NZ	88,929 ^[7]	48,021,660
Africa	25,770 ^[8]	13,915,800
Worldwide	2,500,000 ^[2]	1,350,000,000

1. <https://www.focusonreproduction.eu/article/News-in-Reproduction-China-registry#:~:text=China%20is%20the%20world's%20most,Beijing%2C%20Shanghai%20and%20Guandong>
2. [https://www.rbmojournal.com/article/S1472-6483\(18\)30598-4/pdf#:~:text=Over%208%20million%20IVF%20children,in%20over%20500%2C000%20deliveries%20annually](https://www.rbmojournal.com/article/S1472-6483(18)30598-4/pdf#:~:text=Over%208%20million%20IVF%20children,in%20over%20500%2C000%20deliveries%20annually)
3. <https://academic.oup.com/hropen/article/2020/3/hoaa032/5879305>
4. <https://www.cdc.gov/art/artdata/index.html#:~:text=Based%20on%20CDC's%202019%20Fertility,and%2083%2C946%20live%20born%20infants>
5. <https://www.tripodfertility.com/what-is-the-success-rate-of-in-vitro-fertilization-in-canada/>
6. <https://www.sciencedirect.com/science/article/abs/pii/S1472648320300924>
7. <https://www.fertilitysociety.com.au/wp-content/uploads/Assisted-reproductive-technology-in-Australia-and-New-Zealand-2019.pdf>
8. <https://anara-africa.com/wp-content/uploads/2019/03/Dyer-et-al-2019.pdf>

Finance

12 Months Ended 31 December 2021

Sales up 80%.

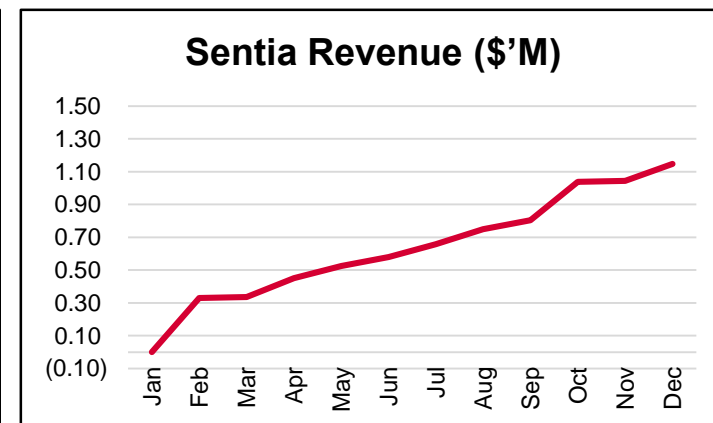
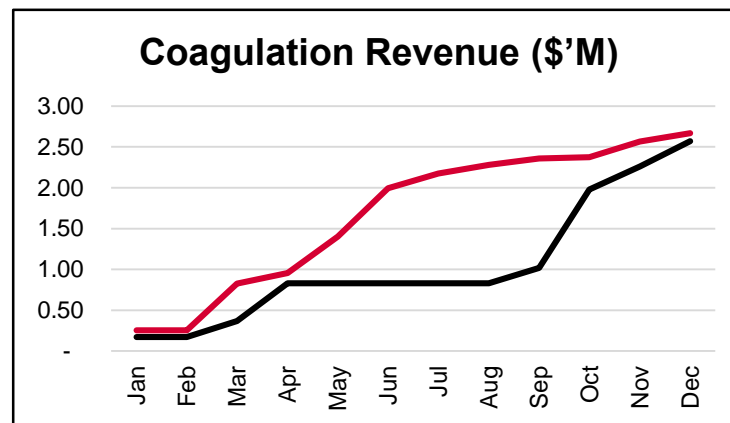
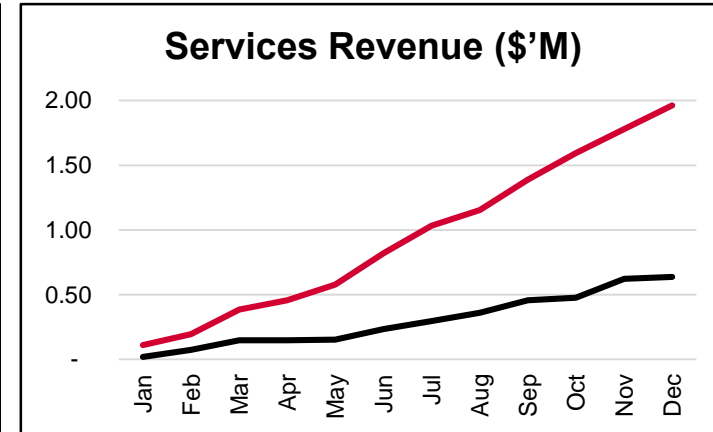
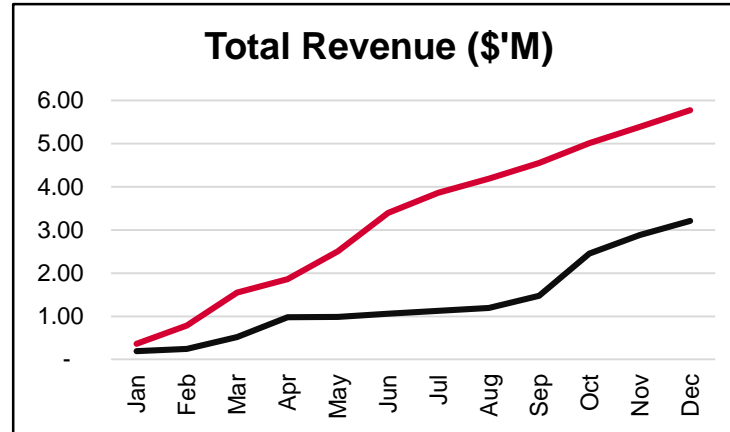
Sentia Sales \$1.15m

Services revenue up 245%.

Gross Profit up 238%.

Coagulation revenue per strip up 27%.

Receipts from customers up 412%.

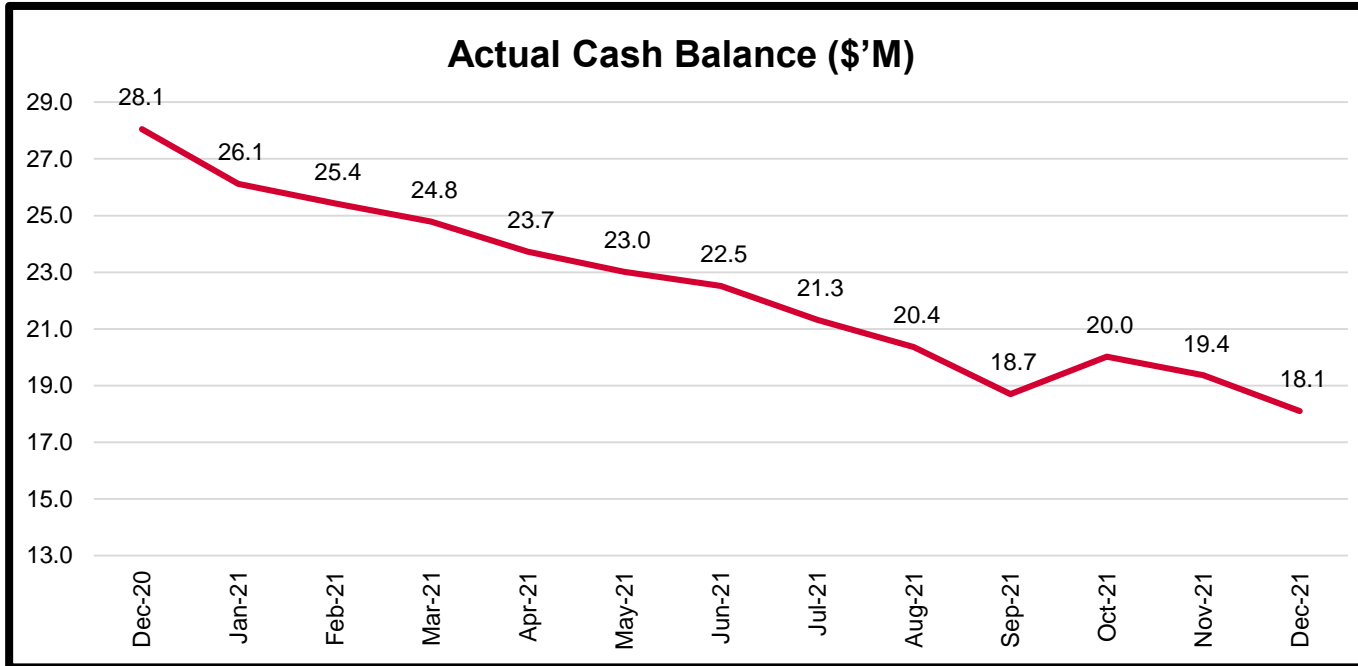


— Actual — Prior Year

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Finance

Strong Cash Position



Use of Funds FY21

Cash used in operations
Cash invested in new products
Other

AUD \$m

4.4
5.5
0.1
10.0

Actual —

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Finance

Profit and Loss Summary FY21

\$m	2021	2020	Change %
Coagulation testing products	2.67	2.57	
Wine testing products	1.15	0.00	
Coagulation testing services	1.96	0.57	245%
Other services	0.00	0.07	
Total revenue	5.78	3.20	80%
Cost of goods sold & services	3.67	2.58	42%
Gross profit (\$)	2.11	0.62	238%
Other expenses			
Depreciation & amortization	2.18	2.23	
R&D expenses	9.28	5.04	84%
Selling, general & administrative	5.61	5.88	
Total expenses	17.06	13.16	30%
Other income			
R&D tax incentive income	3.88	2.83	37%
Other	0.58	2.07	
Total other income	4.45	4.89	(9%)
Net loss	(10.51)	(7.64)	38%

Highlights

- Sales **up 80%**.
- 14 new Distribution Agreements for Sentia.
- Record HRL sales **up 245%**.
- Gross Profit **up 238%**.
- Increase in R&D including clinical trials for Xprecia Prime, Tn Antigen & Aptamers.
- Operating costs tightly managed **down 5%**.

Finance

Cash Flow Summary FY21

\$m	2021	2020	Change %
Cash flows from operating activities			
Receipts from customers	3.97	0.78	412%
Government grants and tax incentives	3.13	3.90	
Payments to suppliers and employees	(17.00)	(12.97)	31%
Net cash used in operating activities	(9.90)	(8.29)	19%
Cash flows from investing activities			
Property, plant and equipment	(0.67)	(0.39)	
Other	0.00	0.03	
Net cash used in investing activities	(0.67)	(0.36)	85%
Cash flows from financing activities			
Proceeds from exercise of options	0.08	0.00	
Proceeds from borrowings	0.02	0.04	
Net cash provided by financing activities	0.10	0.04	116%
Cash and cash equivalents at beginning of period	28.06	37.19	(25%)
Net decrease in cash, cash equivalents and restricted cash	(10.47)	(8.62)	21%
Effect of movement in exchange rates on cash held	0.51	(0.52)	
Cash and cash equivalents at end of period	18.10	28.06	(35%)

Highlights

- Receipts from customers up **412%**.

Finance

Balance Sheet Summary FY21

\$m	2021	2020
Assets		
Cash, cash equivalents and restricted cash	17.29	25.74
Inventories	2.14	1.88
Trade receivables	0.48	0.07
Prepayments and other current assets	4.94	3.70
Total current assets	24.85	31.39
Property, plant and equipment	4.10	4.36
Intangible assets	12.65	14.29
Other non-current assets	2.90	6.34
Total non-current assets	19.65	24.99
Total assets	44.50	56.38
Liabilities		
Trade and other payables	3.91	2.20
Other liabilities	5.49	6.76
Total current liabilities	9.40	8.96
Employee entitlements liabilities	0.03	0.02
Deferred income tax liability	3.05	3.05
Other liabilities	4.41	6.38
Total non-current liabilities	7.49	9.45
Total liabilities	16.89	18.41
Net assets	27.61	37.97
Total equity	27.61	37.97

Highlights

- Increased inventories supports recent international expansion.
- Increased other current assets due to increased R&D rebate receivable.

Finance

Strong Share Price



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Future of UBI

UBI Has


1. Three products generating **sales growth** in **global** markets
Sentia – wine testing platform, Free SO₂ and Malic Acid,
Xprecia Stride – PT/INR coagulation monitoring device,
HRL blood analytics and testing services.
2. **New products** being **launched**
Sentia – testing for Glucose, Fructose, Total Acid, Acetic Acid (others to follow),
Xprecia Prime – approved for sale in Europe. Clinical trials ongoing in USA.
3. Very **strong balance sheet** – (\$18m in cash and no debt).
4. Building motivated workforce in science, sales, supply chain.
5. Significant development opportunities
Cancer monitoring,
Aptamer technology,
 - Instant Covid Test,
 - Fertility.

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END

John Sharman
Chief Executive Officer
Universal Biosensors, Inc

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Appendix 1

Additional information and references

New Product Development

Tn Antigen Cancer Biomarker

Existing cancer biomarkers used to manage cancer patients:

- **PSA** – for prostate cancer has clinical sensitivity (85%) and specificity (30%). Estimated total revenue in 2021 is \$3.5 billion.
- **CEA** – for colorectal cancer to detect tumor growth has clinical sensitivity (55%) and specificity (83%). Estimated total revenue in 2021 is \$3.4 billion.
- **CA 15-3** – for breast cancer patients has clinical sensitivity (54%) and specificity (91%).

If each cancer survivor in remission tested themselves once a month then

Current Remission Monitoring Protocols	
Number of people in remission from carcinomas per year	78,000,000
Average number of tests per person per year	1.5
Number of tests per year	122,252,509
Average cost per test	AUD \$139
Cost of remission monitoring per year	17,010,592,215
Potential Remission Monitoring Protocols Tn Antigen	
If each person in remission is tested monthly with a Tn Antigen test.	
Average number of tests per person per year	12
Number of tests per year	936,000,000
Average cost per test	AUD \$12
Cost of remission monitoring per year	11,232,000,000

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