

19 April 2022

Tn Antigen: Peter Mac Interim Development Clinical Study Results

Universal Biosensors, Inc. (ASX:UBI) is pleased to announce interim results from the Peter Mac sponsored Tn Antigen¹ “Development Clinical Study” (initially announced on 14 September 2021).

UBI is developing a handheld portable Tn Antigen cancer biosensor using a “finger prick” blood test to accurately measure changes to a cancer patient’s tumor status (monitoring of remission and reoccurrence) delivering easier, cheaper, and more frequent tests. The Tn Antigen biosensor test could be used by oncologists and cancer patients in clinics, hospitals, GP clinics or at home.

The results suggest that the Tn Antigen handheld biosensor is potentially more sensitive and more specific than the existing FDA approved Carcinoembryonic Antigen “CEA” biomarker used for monitoring colorectal cancer (sensitivity 55.2% and specificity 83.6%)^[5]. Sales of the CEA biomarker are estimated in excess of \$3 billion pa^[6]. For colorectal cancer subjects, the results are as follows:

| C (n=16), H (n=10)* | Sensitivity (%) ² | Specificity (%) ² |
|---------------------|------------------------------|------------------------------|
| 2 Electrode | 100.0 | 60.0 |
| 3 Electrode | 100.0 | 90.0 |
| CEA | 55.2 | 83.6 |

*C = Cancer (48 samples tested), H = Healthy (30 samples tested). Each patient sample is tested in triplicate

For prostate cancer subjects, the results suggest that the Tn Antigen biosensor is potentially more sensitive and more specific than the existing FDA approved Prostate-specific antigen “PSA” biomarker used for monitoring prostate cancer (sensitivity 85.4% and specificity 30.3%)^[7]. Sales of the PSA biomarker are estimated in excess of \$3 billion pa^[8]. For prostate cancer subjects, the results are as follows:

| C (n=44), H (n=10)* | Sensitivity (%) ² | Specificity (%) ² |
|---------------------|------------------------------|------------------------------|
| 2 Electrode | 92.9 | 60.0 |
| 3 Electrode | 72.7 | 90.0 |
| PSA | 85.4 | 30.3 |

*C = Cancer (132 samples tested) , H = Healthy (30 samples tested). Each patient sample is tested in triplicate

¹ Tn antigen is almost exclusively associated with the development and progression of cancer (carcinomas). Tn antigen is an O-glycan that is very rarely expressed in healthy blood cells or peripheral tissues.

² The "sensitivity" is the true positive rate in cancer subjects, and the "specificity" is the true negative rate in healthy subjects.

The Peter Mac study consisted of subjects (n=66) from 3 tumour streams: Colorectal (n=16), Prostate (n=44) and Breast (n=6) [identified by Peter Mac]. These subjects were supplemented with cancer-free control subjects (n=10) collected by Universal Biosensors.

Initial testing of the Peter Mac retrospective subjects began on UBI's legacy 2 electrode test strip configuration³. Throughout the development process UBI identified that the 2 electrode strip design was not capable of reliably measuring in the sub nano-molar ranges required for the new lubricin-based technology. A new 3 electrode strip⁴ has been designed that allows robust detection of analytes using the lubricin platform. The Peter Mac study was performed on both configuration of test strips.

Although the sample sizes are not statistically significant and patient samples are from pre-screened cohorts, these development clinical results give UBI confidence in the Tn Antigen product and that there is significant improvements to be achieved through continued development of the chemistry and 3 electrode strip.

Due to the small sample size (n=6) of the Peter Mac breast cancer subjects the outcome was inconclusive with little differentiation between cancer and control subjects for the 2 electrode strips although improved differentiation on the 3 electrode strips was observed (data not shown).

As a result of the Peter Mac Development Clinical Trial results, UBI is investing in a new manufacturing line for three electrode test strips. The new manufacturing line will require an engineering upgrade of legacy test strip manufacturing lines and work has begun. This is expected to take between 9 and 12 months to complete with an estimated cost approaching \$2m.

Victorian Cancer Biobank and CIC bioGUNE sponsored study update

UBI expects results from the Victorian Cancer Biobank sponsored study (n=130) on the three-electrode test strip design made on one of the R&D manufacturing lines to be available during H1 2022. UBI will also be retesting clinical samples from the CIC bioGUNE study on the three-electrode test strip design and expects results to be available during H1 2022.

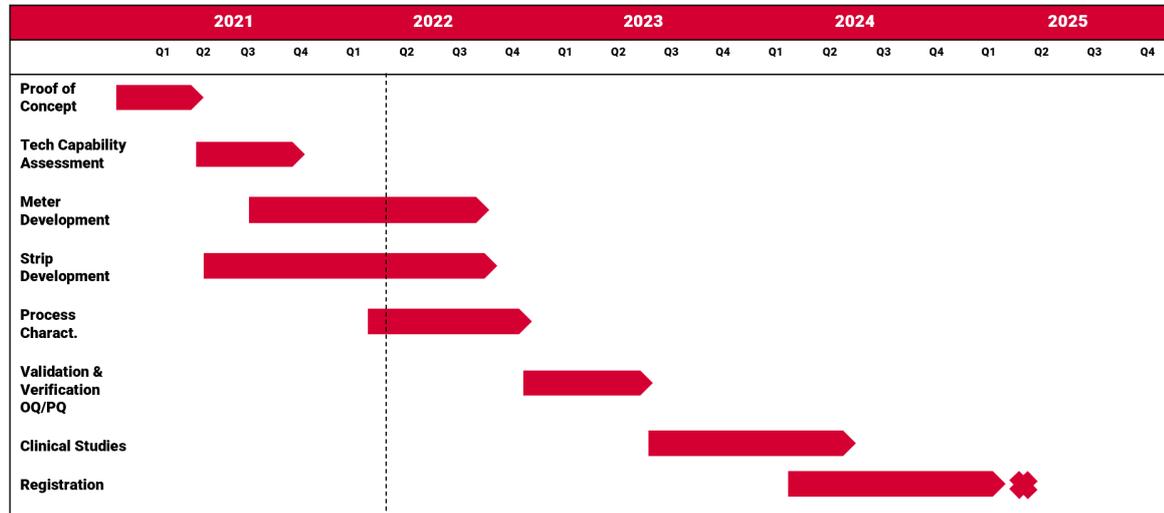
Potential Market

There are 78 million people globally who are in remission from carcinomas^[9,10,11]. Monitoring of subjects in remission is a combination of doctor's visits, blood tests and various scans^[12]. The estimated addressable cancer remission monitoring market is \$17 billion AUD^[9,10,11,12].

³ UBI's legacy IP utilizes 2 "opposing" electrode technology that has served well for analyte detection in the micro-molar concentration range. The UBI technology uses electrode configuration as Working Electrode (**WE**) and Pseudo Electrode (**PE**). In this system the PE plays the role of both the Counter Electrode (**CE**) and the Reference Electrode (**RE**).

⁴ In developing a 3-electrode strip, UBI has incorporated an independent RE which will enable direct control of the current at the CE and the potential at the WE.

Tn Antigen Project Timeline



UBI CEO John Sharman commented

“Our Tn Antigen platform has the potential to materially improve the way in which patients and physicians monitor changes to cancer tumors in a point of care setting, using our hand-held analyzer and a finger prick of whole blood.”

“UBI has extensive experience in handheld analyser / finger prick of blood testing products having already developed blood glucose and coagulation products (together with partners) which have been used to deliver more than 10 billion analytical results to patients and physicians worldwide.”

“This new Tn Antigen product leverages from our 20 years of experience in the field.”

“This first set of results from our Development Clinical Study are extremely promising and reinforces our confidence in moving on with the commercialisation of this product. Importantly our development work continues, and we are confident we can deliver an even better performance from the Tn Antigen biosensor than results achieved to date indicate.”

Enquiries:

John Sharman
 Chief Executive Officer

Announcement authorised by the Board of Directors of Universal Biosensors, Inc.

About Universal Biosensors

Universal Biosensors, founded in 2001, specialises in the design and development of electrochemical cells (strips) used in conjunction with point of use devices that are used in various industries such as healthcare (point of care), wine, food, and agriculture. UBI's ambition is to build a multi product stable of biosensors in large markets which generate ongoing revenue streams. For additional information regarding Universal Biosensors, Inc., refer to: <http://www.universalbiosensors.com>.

About Peter MacCallum Cancer Centre

Peter MacCallum Cancer Centre (Peter Mac) is a world leading cancer research, education and treatment centre and Australia's only public health service solely dedicated to caring for people affected by cancer. They have 3,300 staff, including more than 750 laboratory and clinical researchers, all focused on providing better treatments, better care and potential cures for cancer.

About CIC bioGUNE

CIC bioGUNE is member of the Basque Research and Technology Alliance (BRTA), is a key research center within the national and international scientific landscape and has emerged as a knowledge source in the area of health science. The cutting-edge scientific activity of CIC bioGUNE's researchers explores the interface between Chemistry, Structural, Molecular and Cell Biology, with the aim of developing a more Precise Medicine for the future.

About Victorian Cancer Biobank

The Victorian Cancer Biobank (VCB) is an open-access, not-for-profit tissue resource established by the Victorian Government, Australia and partnered health care providers to facilitate translational research. The VCB provides cancer researchers with a diverse selection of high-quality biospecimens and derivatives, comprehensively annotated with de-identified clinical outcome data.

Forward-Looking Statements

The statements contained in this release that are not purely historical are forward-looking statements within the meaning of the US Securities Exchange Act of 1934. Forward-looking statements in this release include statements regarding our expectations, beliefs, hopes, intentions or strategies. All forward-looking statements included in this release are based upon information available to us as of the date hereof, and we assume no obligation to update any such forward-looking statement as a result of new information, future events or otherwise. Our actual results could differ materially from our current expectations. We cannot assure you when, if at all, the proposals outlined in this release will occur, and the terms of any such proposal are subject to change. Factors that could cause or contribute to such differences include, but are not limited to, factors and risks disclosed from time to time in reports filed with the SEC.

References

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