Universal Biosensors, Inc.
ARBN 121 559 993

1 Corporate Avenue
Rowville Victoria 3178
Australia

Telephone +61 3 9213 9000
Facsimile +61 3 9213 9099
Email info@universalbiosensors.com
www.universalbiosensors.com

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UBI signs new technology licensing deal to commercialise SARS-CoV-2 N-Protein test.

Universal Biosensors, Inc. (ASX:UBI) announces that it has entered into a global exclusive License Agreement with IQ Science Limited for commercialisation of a SARS-CoV-2 N-Protein detection test (which is the virus that causes COVID-19 and herein referred to as COVID-19 Test).

The COVID-19 Test will use UBI's proprietary electrochemical strip and device technology designed to provide a positive or negative result as to a patient's viral status within 30 seconds (based on internal validation work performed to date) from a small saliva sample. UBI's electrochemical test method also has the potential to measure the relative viral load associated with a patient's infection status.

UBI has been working with Dr Shalen Kumar of IQ Science for 6 months performing due diligence on the aptamer technology and the performance quality of IQ Science products. IQ Science was founded by Dr Kumar in 2020. Dr Kumar is a leader in the field of aptamers and a specialist in the generation of ssDNA aptamers capable of binding small molecules for applications in diagnostics platforms. He has over 12 years' experience in the field of aptamers with 8 patent inventions and has successfully developed ELONA assays, Microfluidic systems, Electrochemical biosensing and lateral flow assays. IQ Science has a small number of highly specialised staff working exclusively in the field of aptamer development.

The License Agreement includes the following commercial terms:

- The License is global, exclusive, and perpetual.
- Payment of Commercialisation Fees is triggered on the earlier of receiving a regulatory approval for the COVID-19 Test or generating $1 million of sales from the sale of the COVID-19 Test (these conditions are referred to as the Commercialisation Date).
- Where Commercialisation Fees are not yet payable, a Pre-Commercialisation Fee of $50,000 per year will be paid for a maximum of three years.
- Where Commercialisation Fees become payable, either:
    - a minimum payment of $50,000 in the first year which increases by $100,000 each year up to a maximum of $450,000 in the fifth year and thereafter will be paid; or

- if greater than the minimum payment detailed above, Commercialisation Fees will be calculated based on a percentage of sales typical of transactions of this nature.

- A 'reasonable endeavors' commitment from UBI to commercialise the COVID-19 Test.
- The License will become non-exclusive if the COVID-19 Test is not commercialised within 5 years. Minimum Commercialisation Fees will cease and ongoing Commercialisation Fees payable will be calculated using a reduced percentage of Net Sales to compensate for non-exclusivity.
- The License contains a buy-out option which can be exercised by UBI under certain circumstances at a cost of 6 times the maximum Commercialisation Fees paid in any year over the previous 5 years.
- There are no upfront payments.
- UBI will be responsible for funding and obtaining all regulatory approvals and all commercialisation activities.
- The License has standard termination options but may not be terminated at any time for convenience.

Mr John Sharman, CEO of Universal Biosensors said; "The deal with IQ Science is an important breakthrough for UBI since it will be the first time our platform will use aptamers as a detection technique. Aptamers are a next generation biorecognition element which when combined with our existing technology platform should allow us to detect and measure a large number of targets. Based on what we know is available in the world today, a COVID-19 Test offering an accurate result within 30 seconds of the patient sample will be the first of its kind globally."

Dr Shalen Kumar, Managing Director of IQ Science said; "While aptamers have been in development for many years, the UBI platform is expected to be the first of its kind to offer advanced aptamer-sensing in a handheld portable device. In addition, it is possible the UBI platform will be able to quantify the amount of the virus in the sample which will lead to incredibly valuable data being generated for patients, physicians and governments around the world."

Current rapid antigen tests for COVID-19 have limited sensitivity and take 15 to 20 minutes to prepare a sample and get a result. PCR testing is much more sensitive and accurate but can take days and is very expensive. This makes current tests impractical to use in situations where a COVID-19 Test result is needed instantly in order to make better decisions about safety. This includes when frontline workers and first responders initially engage members of the public, or for high-throughput, broad-based screening at public venues, airports, within the workplace,

and at schools and universities. A COVID-19 Test that could be performed in 30 seconds with high-sensitivity and accuracy would represent a fundamentally new capability to improve public health and safety.

Mr Sharman said; “UBI has completed initial feasibility work on the SARS-CoV-2 N-Protein based test over the last 6 months and we have shown that we can generate a positive or negative COVID-19 response within 30 seconds from a small saliva sample. Our initial feasibility work which comprised approximately 100 tests (carried out as per ISO13485) has shown the necessary sensitivity (1.4 fg/mL) but we still need to confirm the test’s specificity. The test performance is predicted to have similar limits of detection to the Gold Standard RT-PCR methods. There are several manufacturing issues that are being addressed in parallel with the ongoing work to get our N-Protein COVID-19 test strip ready for commercialisation, including confirming the test strip stability.”

Mr Sharman said; “The market for COVID-19 testing is estimated to be US $19 billion in 2021 (refer table below). Recent events, including the response to Omicron, suggest that the demand for COVID-19 testing will remain significant at least for the next 5 years. Subject to further internal and clinical testing, our initial estimate is that we should have a product ready for market in the next 9-18 months.”

End

Enquiries:

John Sharman
Chief Executive Officer
+61 (0) 414 440 680

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. Our wine testing platform Sentia is UBI's newest product which is being launched globally. For additional information regarding Universal Biosensors, Inc., refer to: http://www.universalbiosensors.com.

About IQ Science Limited

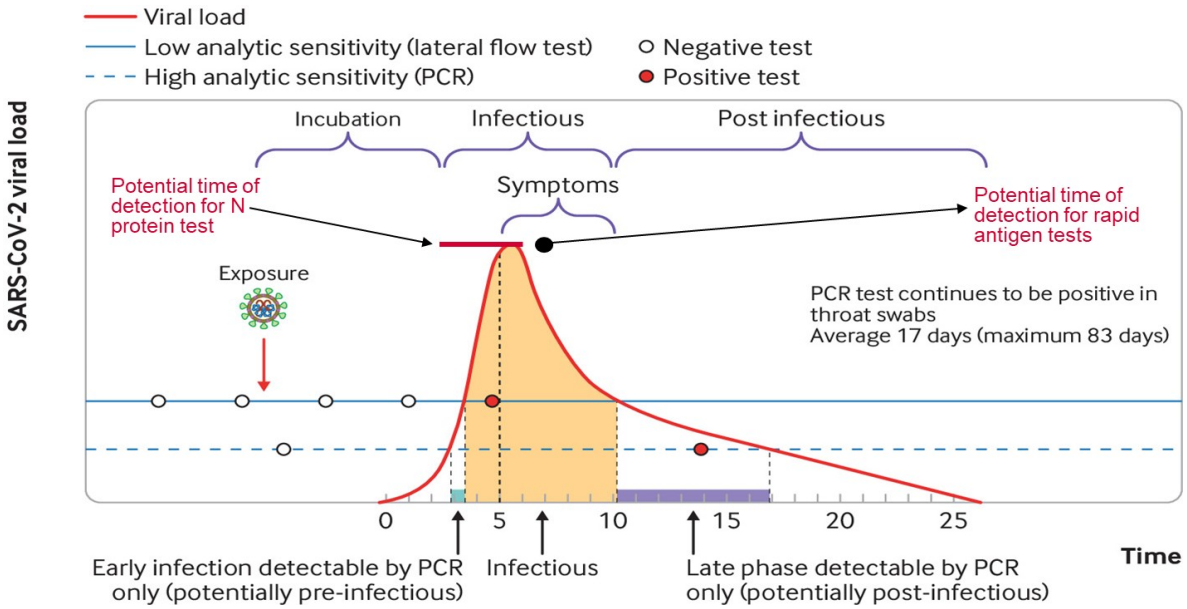
IQ Science Limited (NZBN 9429048598842) was founded in 2020 by its sole director and shareholder Dr Shalen Kumar and is based in Wellington, New Zealand specializing in smart innovative solutions for niche biotech, environmental and health tech markets. IQ Science also holds a portfolio of custom design synthetic DNA based bioreceptors for implementation in point of care sensors. Dr Kumar is an expert in creating aptamer biorecognition elements and is a global leader in the field of aptamers. Dr Kumar is a specialist in the generation of ssDNA aptamers capable of binding small molecules and for applications in diagnostics platforms. He has over 12 years' experience in the field of aptamers with 8 patent inventions in various phases of grant (EU/US/AU/NZ) and has successfully developed ELONA assays, Microfluidic systems, Electrochemical biosensing and lateral flow assays. IQ Science has 5 employees.

How SARS-CoV-2 testing works and standards of detection

RT-PCR techniques are able to detect the virus early in infection, roughly 1-3 days before the onset of symptoms (a similar time to when people start to become infectious). PCR is currently the gold standard for diagnosis of SARS-CoV-2. When performed under laboratory conditions, PCR tests have sensitivities and specificities of over 95%. Time to result is between 24-48 hours.

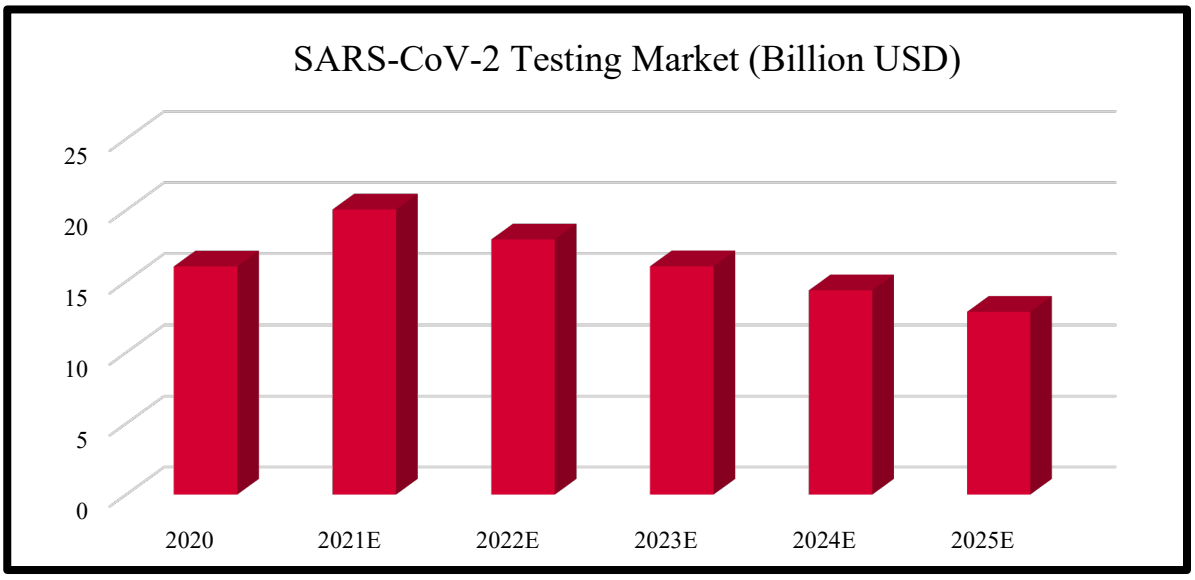
Rapid Antigen tests produce a result within 15-20 minutes. These tests require a higher viral load to record a positive result than PCR tests and usually will provide a positive result 3-5 days later. Rapid antigen tests are generally best performed within the first 7 days from the onset of symptoms.

Mr Sharman said; "A SARS-CoV-2 N-protein test has the potential to detect the virus at similar viral loads and time of infection to PCR. There is also potential to measure the relative viral load associated with a patient's infection which could potentially be correlated to the patient's infectious period."



Source: *Crozier A, Rajan S, Buchan I, McKee M. Put to the test: use of rapid testing technologies for covid19 BMJ 2021; 372 :n208 doi:10.1136/bmj.n208*

SARS-CoV-2 testing market



Source: *Fortune Business Insights*