Uscom

ASX MEDIA RELEASE

SpiroSonic AIR Approved for European CE Mark

- Patent protected wireless lung function testing technology
- Asthma, COPD, and post COVID syndrome
- Spirometry market predicted to double in 12 months
- Globalisation initiative – Europe, SE Asia and US

SYDNEY, Australia, Monday 24th May 2021: Uscom Limited (ASX code: UCM) (the **Company** or **Uscom**) today notifies the market of notice to approve CE mark for the Uscom digital ultrasonic SpiroSonic AIR spirometer. The CE mark is recognition of legal compliance with health, safety and environmental standards set by the European community, and is essential for sale of new medical technologies into the European Economic Area and many SE Asian jurisdictions, a market with a combined population of ~1.4B people.

The Technology:

The SpiroSonic AIR is the leading technology in spirometry utilising Uscom's patented multi-path digital ultrasonic technology, wireless induction charging and BT4 wireless communications. The SpiroSonic AIR connects wirelessly to the mobile phone loaded MyAIR, and SpiroReporter software allowing for remote telemetric and cloud-based diagnosis and monitoring and home care. The BT4 capability will allow simple connection to Uscom's cloud based *Blue Sky eHealth Ecosystem,* providing a new pay per use digital revenue source.

Applications - Post COVID Syndrome:

The SpiroSonic AIR is used for the assessment of asthma, COPD, occupational lung disease and post COVID syndrome. COVID is a respiratory infection often complicated by inflammation and fibrosis which results in impaired lung function. Recent data has demonstrated that 12-17% of severe COVID patients had restrictive lung function on spirometry after 3 months, suggesting serious residual and potentially progressive pulmonary fibrosis with impaired lung function. The evolution of lung dysfunction in survivors of this complex disease is unknown and many previously infected patients may require on going advanced pulmonary monitoring for optimisation of therapy.

Uscom

ASX MEDIA RELEASE

The Market:

Asthma has a worldwide prevalence of ~400m, COPD has a worldwide prevalence of ~300M, and post COVID-19 recovery has a worldwide market of ~300m. Deteriorating environmental air quality and harmful levels of air pollution effect approximately 2B people world-wide. Increasing elderly populations, constrained health budgets, and technological advances in respiratory care devices will drive the spirometry market, and encourage home spirometer monitoring and an increased clinical focus on monitoring respiratory diseases further stimulating demand. Following the COVID pandemic global Spirometry demand is predicted to increase ~160% over the next 6 years from $2.6B to $6.5B.

Regulatory Approval:

The regulatory approval of medical devices is becoming increasingly complex and time consuming and this notice of CE Mark comes at the end of an 18-month process which has been complicated by the COVID-19 pandemic and repeated changes in CE regulations. This complexity, a liability to incumbents, acts as an extra barrier to entry for competitors.

Commentary:

Executive Chairman of Uscom, Professor Rob Phillips said *"The spirometry market is predicted to increase ~160% over the next 6 years to $6.5B, making this a very exciting time for Uscom to bring the world leading SpiroSonic AIR to market. The CE mark delivers our SpiroSonic technology to Europe and most SE Asian markets and is part of Uscom's diversification and globalisation initiatives as we continue to progress US FDA and China NMPA. The SpiroSonic AIR is accurate, easy to use, and provides research quality non-invasive lung function testing for patients with asthma, COPD, occupational lung disease and post COVID syndrome, and can be used in the lab, clinic or home. The SpiroSonic AIR has advanced digital capabilities, making it an ideal foundation sensor for Uscom's new Blue Sky eHealth Ecosystem, CRO's and other international groups developing novel pulmonary care telemetric home use management models. The SpiroSonic AIR will be rolled out for sale into the growing Uscom distribution networks in Europe and SE Asian jurisdictions."*

Uscom Devices:

Uscom manufactures and markets the USCOM 1A haemodynamic monitor, the Uscom BP+, central blood pressure monitor, and the Uscom SpiroSonic digital ultrasonic spirometers, and the VENTITEST and VENTITEST-S ultrasonic ventilator calibrators for optimising respiratory device performance.

References:

https://spirosonic.com
Arnold DT, Hamilton FW, Milne A, et al. Patient outcomes after hospitalisation with COVID-19 and implications for follow-up; results from a prospective UK cohort. medRxiv preprint doi: https://doi.org/10.1101/2020.08.12.20173526
https://www.marketresearchfuture.com/reports/spirometry-market-6539

Uscom

ASX MEDIA RELEASE

About Uscom

Uscom Limited (UCM): An ASX listed innovative medical technology company specialising in development and marketing of premium non-invasive cardiovascular and pulmonary medical devices. Uscom has a mission to demonstrate leadership in science and create noninvasive devices that assist clinicians improve clinical outcomes. Uscom has three practice leading suites of devices in the field of cardiac, vascular and pulmonary monitoring; the USCOM 1A advanced haemodynamic monitor, Uscom BP+ central blood pressure monitor, and the Uscom SpiroSonic digital ultrasonic spirometers. Uscom devices are premium resolution, noninvasive devices which deploy innovative and practice leading technologies approved or submitted for FDA, CE, CFDA and TGA regulatory approval and marketing into global distribution networks.

The USCOM 1A: A simple to use, cost-effective and non-invasive advanced haemodynamic monitor that measures cardiovascular function, detects irregularities and is used to guide treatment. The USCOM 1A device has major applications in Paediatrics, Emergency, Intensive Care Medicine and Anaesthesia, and is the device of choice for management of adult and paediatric sepsis, hypertension, heart failure and for the guidance of fluid, inotropes and vasoactive cardiovascular therapy.

The Uscom BP+: A supra-systolic oscillometric central blood pressure monitor which measures blood pressure and blood pressure waveforms at the heart, as well as in the arm, information only previously available using invasive cardiac catheterisation. The Uscom BP+ replaces conventional and more widespread sub-systolic blood pressure monitors, and is the emerging standard of care measurement in hypertension, heart failure and vascular health. The Uscom BP+ provides a highly accurate and repeatable measurement of central and brachial blood pressure and pulse pressure waveforms using a familiar upper arm cuff. The BP+ is simple to use and requires no complex training with applications in hypertension and pre-eclampsia, heart failure, intensive care, general practice and home care. The Uscom BP+ is supported by the proprietary **BP+ Reporter**, an innovative stand alone software solution that provides a digital platform to archive patient examinations and images, trend measure progress over time, analyse pulse pressure waves and generate summary reports.

Uscom SpiroSonic digital multi-path ultrasonic spirometers: High fidelity, digital, pulmonary function testing devices based on multi path ultrasound technology. They require no calibration, are simple to disinfect, and are simple and accurate to use providing research quality pulmonary function testing in small hand held devices that can be used in research, clinical and home care environments. The devices can be coupled with mobile phone apps and proprietary SpiroSonic software, **SpiroReporter**, with wireless interfacing to provide remote tele-monitoring of pulmonary disease. The devices are specialised for assessment of COPD, sleep disordered breathing, asthma, occupational lung disease and monitoring of pulmonary therapeutic compliance.

VENTITEST digital ultrasonic ventilator testing solution is a new system for testing ventilators. All ventilators require calibration to maintain the accuracy with which they measure the pressure, flow and volume of air they deliver. VENTITEST and VENTITEST-S, based on advanced SpiroSonic technology provides a testing solution that provides for simple and accurate testing, archiving, analysis and reporting to optimise ventilation performance.

For more information, please visit: www.uscom.com.au

Uscom Contacts

Rob Phillips
Chairman
rob@uscom.com.au

Brett Crowley
Company Secretary