Uscom

ASX MEDIA RELEASE

Regulatory Approvals for Three Uscom Devices

SYDNEY, Australia, Monday 26th August 2019: Uscom Limited (ASX code: UCM) (the **Company** or **Uscom**) today announced the receipt of Conformité Européenne (CE) certification of three of its SpiroSonic digital ultrasonic spirometry devices. A CE certificate is required to sell products within the European Economic area and is a declaration by the manufacturer that the product meets the European Directives. A number of other countries worldwide use CE certification as a regulatory requirement to sell in their jurisdictions.

The CE approval was issued for the Uscom SpiroSonic FLO, SMART and MOBILE devices. The re-approval was required following the relocation of Uscom Kft to an expanded facility in Budapest to accommodate an anticipated increased manufacturing demand once Chinese NMPA certification is received.

There was an eight month interruption to manufacturing and sales while the CE certification process was conducted by the European authority. Despite the interruption, Uscom Kft increased total income by 47% in FY 2019. This growth was partly driven by structural changes, product rebranding and repricing, and increased international partnerships, as well as EuroGrant R&D projects for development of new products and clinical applications. The new digital ultrasonic SpiroSonic AIR device is still undergoing CE certification. Uscom has also initiated sales, marketing, and clinical and technical support activities for all Uscom products through Uscom Kft, creating a new Uscom European hub. Uscom Kft will also continue its R&D and manufacturing functions.

Executive Chairman of Uscom, Associate Professor Rob Phillips said "The CE certification of our digital ultrasonic spirometers allows us to sell into the European, and most SE Asian and Middle Eastern markets. We have a number of partners keen to advance sales in these jurisdictions who have been waiting on the new CE approvals. Regulatory approvals are a significant focus of our international business, with processes becoming more complex and time consuming, despite Uscom specialising in non-invasive technologies. However we are expecting the flow of new approvals from Europe and China to continue over the next 12 months, including approval for our new and exciting SpiroSonic AIR device. We anticipate this device will significantly impact the digital home care asthma and COPD market once approved."

Uscom manufactures and markets the USCOM 1A, the Uscom BP+, and the Uscom SpiroSonic digital ultrasonic spirometry technologies. These premium digital devices are changing the way we diagnose and treat cardiovascular and pulmonary diseases, including hypertension, heart failure, asthma, COPD and sleep disorders. These devices and technologies provide vital guidance for optimising management of sepsis and the administration of fluid, inotropes and vasoactive therapies in critical care monitoring. They can also be applied in clinical and home care diagnosis of asthma and COPD, and monitoring the effects of treatment.

About Uscom

Uscom

ASX MEDIA RELEASE

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 applications and proprietary SpiroSonic software platforms with wireless interfacing to provide remote tele-monitoring of pulmonary disease. The devices are specialised for assessment of COPD, sleep disordered breathing, asthma, industrial lung disease and monitoring of pulmonary therapeutic compliance. The SpiroSonic devices are supported by the proprietary **SpiroReporter**, an innovative stand alone software solution that provides a digital platform to archive patient examinations and images, trend measure progress over time, analyse spirometry outputs and generate summary reports.
For more information, please visit: www.uscom.com.au

Uscom Contacts

Rob Phillips
Executive Chairman
rob@uscom.com.au

Brett Crowley
Company Secretary