



Uscom

ASX MEDIA RELEASE

TGA for Uscom SpiroSonic Digital Spirometers

Uscom advanced digital ultrasonic SpiroSonic lung function devices receive regulatory listing for sale in Australia

SYDNEY, Australia, Thursday 13th March 2017: Uscom Limited (ASX code: UCM) (the **Company** or **Uscom**) announced that the Uscom SpiroSonic product range of lung function monitors have been listed on the Australian Regulator of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA). This listing allows sale of the Uscom high fidelity, digital ultrasonic SpiroSonic pulmonary function monitors as a class IIA device.

Key Points

- TGA is Australian regulatory authority for therapeutic goods including medical device and listing is required before sale in Australia
- Chronic respiratory diseases (asthma, COPD and sleep apnoea) are common and increasing worldwide
- Uscom SpiroSonic devices are high fidelity pulmonary function testing devices used in home care, clinics and advanced pulmonary testing laboratories to diagnose and manage asthma, COPD and sleep apnoea
- SpiroSonic devices have recently received CE (European) approval and are currently in process for CFDA (China) and FDA (US) approvals
- Uscom BP+ and BP+ Reporter are also in process for global regulatory approvals

Regulatory approvals are essential for permission to sell in almost all global jurisdictions and are evaluated in terms of safety and efficacy. The SpiroSonic devices are listed by the ARTG with the identifier 291176. The SpiroSonic devices already have CE (Europe) and now TGA approval, and are in process for CFDA (China) and FDA (USA). The Uscom BP+ and BP+ Reporter are also undergoing the same processes, but because of precedent approvals the timeline may be shorter. However the duration of the regulatory processes vary with jurisdiction and product, and are therefore uncertain. Uscom has already appointed an Australian distributor to begin sales, and multiple new European distributors, and is looking to appoint new US and SE Asian distributors.

Executive Chairman of Uscom, Associate Professor Rob Phillips said, *“Regulatory approval is the path to sales and revenue for our new products, and each new approval represents another regional revenue stream. Our strategic objective is to bring the SpiroSonic devices and the BP+ central blood pressure devices to global markets and anticipate receiving regulatory approvals for all products in all jurisdictions intermittently over the next 12mths. Our current growth has been predominantly attributable to USCOM 1A sales, and so the approval for sale of additional devices in additional jurisdictions represents incremental future revenue opportunities and growth drivers. We are building a real company aiming to combine blue sky, practice changing science with hard measures of sales, revenue, profitability and shareholder distributions. Regulatory approvals are vital steps in this process and a key focus of our operations.”*



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About Uscom

Uscom Limited (UCM): An ASX listed innovative medical technology company specializing 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 hemodynamic 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, display trend measures over time, analyse blood pressure waveforms and values, and generate patient reports.

Uscom SpiroSonic digital multi-path ultrasonic spirometers: High fidelity, digital, pulmonary function testing devices based on multi path ultrasound technology. They are simple and accurate to use and provide 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, display trend measures over time, analyse spirometry outputs, and generate patient reports.

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

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