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ASX RELEASE

AIR FDA 510K Filed and New US Distribution

- US FDA filed for multiple devices including the SpiroSonic AIR
- Technology solutions for Asthma, COPD, and COVID
- FDA 510K submission filed with >2000 pages
- Sovereign Medical appointment for US East Coast distribution

Thursday 28th April 2022: Uscom Limited (ASX code: UCM) (the **Company** or **Uscom**) advises that Uscom has filed a 510K application for clearance of SpiroSonic spirosonometric devices and accompanying SpiroReporter apps and software to the Centre for Devices and Radiologic Health of the US Food and Drug Administration (FDA). The submission has been received by the FDA and allocated a processing number (K220982) with a series of responses due over the next 60 days. FDA clearance, if received, will allow for sale of the SpiroSonic technologies in the US. The SpiroSonic devices contain patent protected spirosonometry technology which includes digital vocal user guidance, phonic outputs and auto-diagnostic interpretation.

Background:

Asthma, Chronic Obstructive Pulmonary Disease (COPD), and more recently COVID, short and long, are pulmonary diseases that can cause substantial morbidity and mortality. Spirometry is an established method of measuring lung function and selecting optimal treatment, but current technology is limited by poor patient compliance, inaccurate measurements and complexity of use and difficulty of device maintenance. SpiroSonic digital spirosonometry is Uscom's new approach to ultrasonic spirometry specialised for simplified, more hygienic and more accurate measurement and ideal for widespread adoption.

Operations:

The FDA review process follows a strict path including acceptance, review, substantive review, and decision, over a period of 90 days, excluding any request for additional information. The submission included more than 2,000 pages of supporting documentation and test results. The SpiroSonic devices have CE clearance in Europe, and are mid NMPA review in China with clearance expected in approximately 6 to 12 months.

The global Spirometry market is predicted to grow at 11.1% CAGR to reach $1.28b USD by 2025 driven by increasing incidence of respiratory disease, increasing age of population and the shift of spirometry devices toward smart phone-based data acquisition.

The incidence of pulmonary fibrosis as a complication of acute and long COVID will also drive future demand for home use spirometry with an estimated population of 500m to 1b patients infected worldwide. The current market is predominantly clinics and hospitals, but shifting to the more cost-effective delivery of lung performance management in home care with eHealth.

There are also a number of emerging and specialised lung function organisations, with many linked to pharma testing for effectiveness of new pulmonary drugs, all of which are based on back-end software and analytics but which require premium front end sensors. It is in this space that Uscom has collaborated with Koneksa Health to create innovative solutions for monitoring pulmonary physiology. Uscom's digital Spirosonometric technology provides the stand-alone ultrasonic lung function testing with innovative on-board analytics and guidance.

Uscom has also appointed Sovereign Medical to distribute its devices on the US East Coast from New York to Florida further enhancing its nascent US distribution. Sovereign Medical specialise in distribution into critical care, respiratory care, emergency medicine, sleep medicine, maternal health, and infusion therapy fields, all aspects of care Uscom devices address. Uscom's US team has begun

training 12 of Sovereign's specialty team on Uscom products, and expect to launch sales in the next two months. The agreement is for the sale of 40 USCOM 1A units over a 3-year term and if forecasts are met is anticipated to generate profitability for the US subsidiary, creating a material change for Uscom Limited.

Commentary:

Executive Chairman of Uscom, Professor Rob Phillips said *"Product diversification, global markets, and operational agility are key to global corporate success in uncertain times, and this US FDA filing and US distribution appointment reflects this strategy.*

Lung disease is one of the most common causes of human morbidity and mortality, and the US is the world's largest medical device market so this filing and expansion of distribution is predicted to be material for the Uscom. The pulmonary monitoring market is in a state of rapid growth, moving from clinical monitoring to home care and eHealth. Uscom's newly patented Spirosonometric technology and SpiroSonic AIR devices provide accurate hardware, innovative software, and a solution for the major limitations of current spirometry including reliability, effective disinfection and repeated calibration. Uscom has been working with Koneksa to optimise the system we deliver for research and advanced home care for over 2 years, and FDA clearance will allow us to initiate partnerships with US Pharma organisations seeking precision lung function assessment of the effectiveness of their drugs. Koneksa are specialists in this space with a number of large and respected partners ready to begin research once the SpiroSonic AIR receives FDA clearance.

Importantly the Uscom European R&D team have developed and patented a number of spirometric innovations to significantly enhance the performance and ease of use of our spirometers making them more accurate and simpler to adopt for children and adults with asthma, and all patients with persistent symptoms following COVID.

The FDA clearance will allow us to actively sell into the US, and, combined with our NMPA in China – which is mid review, will enable Uscom SpiroSonic devices to establish clinical and commercial leadership in spirometry and lung function monitoring world-wide. Regulatory clearance, particularly with the FDA, is becoming increasingly expensive, costly and complex, and as such is a significant value add once received, and a barrier to entry for competitors.

The appointment of Sovereign Medical as specialised East Coast distributors will compliment this clearance and build out our US market access. The agreement adds 12 new sales staff to our growing US footprint as the US rebounds from 2 years of restrictions due to the COVID pandemic, and as FDA clearance is received for the SpiroSonic suite of pulmonary products."

References:

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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

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This announcement is approved for release to the ASX by the Board of Uscom Limited.