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Uscom expands China operations, secures key appointments

SYDNEY, Australia, Monday 28th May 2018: Uscom Limited (ASX code: UCM) (the **Company** or **Uscom**) has secured two key new appointments as it progresses through the China Food and Drug Administration (CFDA) regulatory process and executes on its expansion strategy in China.

Ms Teresa Guo has been appointed Uscom's Director of China Operations. Beijing-based, Ms Guo has an MSc from the University College London, and was most recently the Medical Communications Officer for Bayer Healthcare in Beijing. Ms Guo was previously the International Business Assistant and Product Specialist in Sihuan Pharmaceutical Holdings Group in Beijing where she was engaged in project management and quality analysis.

Ms Guo has experience in multiple aspects of the China medical industry chain including project management, CFDA regulatory affairs, China patents and trademarking, marketing and distribution, medical affairs and business development. Ms Guo is focused on establishing new Uscom distribution channels in China in preparation for the CFDA certification of BP+ and SpiroSonic devices. Ms Guo will oversee Uscom operations in China, including supervising patents and trademarking, managing CFDA regulatory submissions and relationships, managing Chinese distribution and sales channels, and co-ordinating academic and marketing activities in China.

Uscom has also appointed Mr Curt Grosse as Vice President of North American Sales for Uscom Inc., the wholly-owned US subsidiary of Uscom Limited. Mr Grosse, based in North Carolina, has a Bachelor of Science and Bachelor of Business Administration and has over 20 years' experience in medical device and capital equipment sales, having previously worked with Edwards Lifesciences, Covidien, Olympus, US Surgical Corp and Cheetah Medical. Mr Grosse has excellent connections on the US east coast and is currently building a national network of distributors to expand US sales and revenue.

Uscom CEO Associate Professor Rob Phillips said: *"The expansion of our China operations continues to be the focus of our commercial activities. Ms Guo is experienced in negotiating the regulatory, commercial, legal and social environment surrounding sales and distribution of medical devices in China. Ms Guo's contribution is vital as we approach the final stages of CFDA which will lead to the sale of our seven new products in China over the next 12 months. With the relationships and experience provided by Ms Guo, our China footprint and growth targets are increasing. Uscom devices are world leaders in cardiac, vascular and pulmonary monitoring, and it is cardiac, vascular and pulmonary diseases which are increasing most rapidly in China. The appointment of Mr Grosse as head of sales and marketing for the US will diversify our international business and generate sales growth in the largest medical device market in the world. Mr Grosse, while focusing on USCOM 1A sales, is developing a national sales and distribution strategy in preparation for the US FDA certification of our new BP+ and SpiroSonic products later in the year."*

Ms Guo said: *"The commercial opportunities for Uscom in China are many, ranging from tertiary hospitals to home care for all Uscom products, and this operational expansion allows us to prepare the market for the CFDA certification of our new BP+ and SpriroSonic devices. We will continue to expand support for our USCOM 1A distributors as we actively advance conversations with new distributors so that we can immediately begin selling our new devices once CFDA is received. This is planned to drive new Uscom revenue and transform the Uscom China business."*

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The expansion of Uscom China operations is in preparation for CFDA certification of the BP+ and SpiroSonic product suites. CFDA regulatory certification is required to sell medical devices into China, and may take more than 2 years from start to finish, while certification is valid for five years. The process entails approximately 12 sequential steps, and requires guidance by China based regulatory and legal agents.

All Uscom devices, are currently in various stages of CFDA submission.

1. The USCOM 1A is currently CFDA approved and under re-application
2. The BP+ and SpiroSonic devices are new submissions. Chinese agents have been appointed and initial CFDA consultations completed. The product dossiers are currently being submitted for final committee review

Uscom anticipates CFDA approval for all its products within the next 6-12 months.

Uscom devices are sector leading non-invasive devices for cardiac, vascular and pulmonary monitoring and assist management of heart failure, hypertension, sepsis, asthma and COPD. These diseases are responsible for approximately 75% of global mortality, and are rapidly increasing in incidence in China.

References:

https://www.china-certification.com/en/process-of-cfda-application/

https://www.tuv-sud.com/industries/medical-devices-healthcare/market-approval-amp-certification/china-market-access

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About Uscom

Uscom Limited (UCM) is 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 is 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+ is 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, 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, trend measure progress over time, analyse pulse pressure waves and generate a summary report.

Uscom SpiroSonic digital ultrasonic spirometers are 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, trend measure progress over time, analyse spirometry outputs and generate a summary report.

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

Uscom Contacts

Rob Phillips
Executive Chairman
rob@uscom.com.au

Brett Crowley
Company Secretary
secretary@uscom.com.au