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Uscom BP+ Central Blood Pressure Monitor Released

10 year international collaboration brings world leading technology to market

- **Targeting new \$5B hypertension market**
- **Orders and distribution in place**
- **Device already used on International Space Station, Mt Everest with UK Military, and in Pharma pilot hypertension studies**

SYDNEY, Australia, Monday 30th October 2017: Uscom Limited (ASX code: UCM) (the **Company** or **Uscom**) has released the Uscom BP+ central blood pressure monitor, the world's most advanced blood pressure device. The patent protected BP+ technology has the potential to change the way hypertension and heart failure are monitored and managed, and is the culmination of a collaboration by a team of international clinicians, engineers and software technicians spanning over 10 years.

Uscom acquired the BP+ technology in 2013 for approximately \$1M in UCM script from Pulsecor, and has spent a further \$2M+ and nearly five years preparing it for market. In that time the device has been developed in house by Uscom engineers and consultants with acquisition and development costs entirely funded by operational cash flow and investors.

The Uscom suprasystolic oscillometric technology was developed by Uscom Medical Advisory Board Member Professor Nigel Sharrock of the New York Hospital for Special Surgery and Ass Professor Andrew Lowe of the Bio-medical Engineering Department at the Auckland University of Technology.

The Uscom BP+ is a digital technology which provides direct measures of blood pressure (BP) and pulse pressure waves at the heart (central BP), as well as basic BP information current devices provide, thus the device is called the BP+. Previously such measurements were only available using invasive cardiac catheters, but this can now be provided noninvasively by the Uscom BP+.

As a companion technology for the BP+, Uscom has developed the proprietary BP+ Reporter, an innovative standalone software solution that provides a digital platform to archive patient files and generate summary reports. The combined devices provide a digital and connectable solution to most electronic record keeping systems.

The development and validation of sophisticated science is unpredictable and the creation and release of the BP+ represents the culmination of more than ten years of rigorous scientific collaboration combined with many scientific and technical resources inside and outside Uscom including in Germany, Belgium, the UK, NZ and the US.

Since acquisition, the process has included a redesign of the beta BP+ device to include new hardware and software, and development of new cuff technology, all of which required extensive effectiveness testing and validation. External auditing was conducted of the Uscom quality system and the BP+ technical file. These files are necessary for the BP+ to be compliant with the Medical Device Directives for CE and are the foundation technical documentary requirements for worldwide regulatory. Global regulatory approvals, already initiated, are expected to be received in from 2 to 12 months after product release. As part of the development program the BP+ has been prepared for manufacturing using subcontract manufacturers and suppliers to ensure reliable on going product supply. This complex and rigorous process is the path to market and what ultimately creates value in medical devices.



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The device and algorithms have been clinically tested against invasive cardiac catheters in adults at Mons University Cardiac Catheterisation Laboratories, and in children down to 1 year of age at the Great Ormond Hospital for Sick Children in London. Clinical applications are being explored on the International Space Station, Mount Everest, with major Pharma companies to assess effectiveness of new drugs, and in pharmacy clinics in the UK.

The global hypertension device market is a new opportunity for Uscom and is reported to be \$5B USD, while \$74B pa is reportedly spent on hypertension in the US alone. So the scale of the potential Uscom revenue growth from BP+ sales is both substantial and uncertain, and will only become clear over the coming few years. While Uscom plans to retain the BP+ technology as a foundation for accelerated revenue growth over the next decade, it could also be strategically licensed or on sold into international distributors.

The device has attracted significant market attention and Uscom has new distribution agreements and is in discussions with a number of major distributors from US, Europe and SE Asia regarding inclusion of BP+ in their distribution portfolio. The China State owned CIIC Shanghai already has an importation and distribution agreement for China and their distribution arm, Sense Medical, is currently appointing a sub-distributor network for in hospital and out of hospital sales.

Executive Chairman of Uscom, Associate Professor Rob Phillips said *"Uscom is now a technologic leader in the in the \$5B worldwide hypertension market, an entirely new revenue source for the company. The BP+ development has been a significant cash flow cost over the last 3 years, but now investors are poised to yield from this commercial opportunity, the scale of which is yet to be determined. We are incredibly proud of the Uscom BP+ and BP+ Reporter and the effectiveness with which we have brought them to market. Hypertension occurs in approximately 1 in 3 adults worldwide and less than 50% have their disease controlled when monitored using current subsystolic technology; the BP+ has been developed to improve this. The path to market for the BP+ like much world leading science, has taken longer and cost more to develop than anticipated, requiring the most diligent and rigorous scientific focus by our team over nearly five years. The BP+ can be used as a standalone technology for improved hypertension care, or accompanied by the BP+ Reporter for more detailed and specialised applications such as pre-eclampsia and heart failure."*

Simple cuff measured BP monitoring of the arm has been a cornerstone of clinical medicine since 1896, and arm pressure used as a proxy for BP at the heart ever since. However the latest research has confirmed that central BP is superior to arm BP for diagnosis, therapeutic guidance and risk prediction, causing excitement among clinicians and an emerging interest in monitoring central BP. Some devices measure arm and wrist pressure with a cuff or tonometer and then estimate the central BP from this using a generalised transfer function. However this approach is based on and limited by the relative inaccuracy of the subsystolic arm measurement, while the patent protected Uscom BP+ method is novel in making non-invasive and direct pressure measurements into the heart while the arm arteries are occluded allowing for more direct and accurate measurements of BP at the heart.

References: 1. Lin ACW, Andrew Lowe A, Sidhu K, Harrison W, Ruygrok P, Stewart R. Evaluation of a novel sphygmomanometer, which estimates central aortic blood pressure from analysis of brachial artery suprasystolic pressure waves. J Hyperten 2012;30:000–000. DOI:10.1097/HJH.0b013e3283567b94 2. Stoner L, Lambrick DM, Westrupp N, Young J, Faulkner J. Validation of Oscillometric Pulse Wave Analysis Measurements in Children. Am J Hypertension 2014, doi:10.1093/ajh/hpt243 3. McEniery CM, Cockcroft JR, Roman MJ, Franklin SS, Wilkinson AB. Central blood pressure: current evidence and clinical importance. Euro Heart J 2014;doi10.1093/euroheartj/ehv565 4. Sharman JE, Avolio AP, Baulmann J, et al. Validation of non-invasive central blood pressure devices: ARTERY Society task force consensus statement on protocol standardization. Euro Heart J 2017;0:1–10. doi:10.1093/eurheartj/ehw632.



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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 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

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