

# Material increase in USCOM 1A orders in China

- Uscom is updating its manufacturing strategies to meet an increased demand from China over the past five weeks.
- USCOM 1A manufacturing is initially planned to be increased by 121% for FY Q3
- The National Health Commission of the People's Republic of China Coronavirus
   Protocol advocates haemodynamic monitoring for severe coronavirus cases (released
   5th February 2020)
- The USCOM 1A haemodynamic monitor is widely used in China to optimise management of infections in neonates, children, pregnancy, adults, and the elderly
- Numerous USCOM 1A units have been installed in Chinese hospitals, with more currently in installation
- The first Chinese Hospital to be equipped with an USCOM 1A specifically for management of Coronavirus was commissioned on 23<sup>rd</sup> January 2020
- The USCOM 1A recently received a five-year NMPA approval for sale into the China market
- The situation in China is rapidly evolving and Uscom will continue to inform investors with further details and material developments as they become available

**SYDNEY, Australia, Monday 10<sup>th</sup> February 2020:** Uscom Limited (ASX code: UCM) (the **Company** or **Uscom**) today announced a material increase in USCOM 1A orders from China during the past five weeks, with some devices being specifically installed for the monitoring of hospital patients diagnosed with Coronavirus (2019-nCoV).

The USCOM 1A haemodynamic monitor was developed to optimise management of infectious diseases, with many USCOM 1A units widely installed in Chinese hospitals with most deployed in the management of sepsis.

In response to this epidemic, The China National Health Commission released the new 5<sup>th</sup> Edition of the National Protocol for the Detection and Management of Coronavirus on the 5<sup>th</sup> February 2020. These Protocols recommended haemodynamic monitoring of severe and critically severe cases of Coronavirus.

Uscom is planning to increase manufacturing output by approximately 121% on 10 year average outputs to meet the anticipated demand for H2. Unit orders for the first five weeks of 2020 are up 124% compared to the first full two months of 2019, and prior to the Government announcement.



Despite the jump in new USCOM 1A orders the Company is unable to provide further details or specific numbers due to the rapidly evolving situation in China. Uscom will continue to update the market with material information as it becomes available.

Executive Chairman of Uscom, Associate Professor Rob Phillips said: "The USCOM 1A is a specialised technology developed to simplify diagnosis and management of infectious diseases and is now being implemented widely in China under new National Government released Coronavirus Protocols to save the lives of the most seriously ill patients. Over the last 15 years we have installed devices, trained operators and educated doctors across China on the best method for managing circulatory support in sepsis in neonates, children, pregnancy, adults and the elderly. This is a dangerous epidemic in the world's most populous country, and the Government of China is acting decisively to limit the spread and impact of the disease by providing guidelines, equipment and personnel to most effectively care for the 1.4B people of China. This epidemic is forcing our technology from the hands of a small number of infectious disease experts into the hands of physicians dealing day to day with tens of thousands of patients with deadly infections. Uscom has a wholly owned subsidiary in Beijing with staff, partners and friends in China, and our wishes are with the people of China at this difficult time and we are committed to supporting them in every way possible; Uscom is in China and with China. Events are moving very quickly in China and I will continue to keep shareholders updated as appropriate."

## Background:

## Coronavirus:

Is a serious infectious virus reported in neonates, children, pregnant women, adults and the elderly that is complicated by acute pneumonia and has a mortality rate ~2%. The virus was first identified in Wuhan, China, in mid-December and currently there are ~40,000 confirmed cases and ~900 deaths in China across all provinces, numbers that are continuing to increase rapidly, while spreading into at least 25 countries. There currently remains no vaccine for the disease, and while many patients may only experience symptoms of a mild cold and 98% recover, serious cases require ICU care, haemodynamic monitoring and respiratory support to prevent death. The cause of death is cardiovascular pulmonary failure, so an accurate and non-invasive haemodynamic monitor which can rapidly and accurately diagnose abnormalities and guide cardiovascular treatment in large numbers of patients is critical.

#### WHO Declaration:

WHO has classified this outbreak a public health emergency of international concern six weeks after its first identification.

#### Chinese Government Strategy:

The epidemic has been rapidly prioritised by Chinese authorities and Mr Ma Xiaowei the Director of the Chinese National Health Committee and Secretary of the Party Committee addressed the press on 3.01.45pm on 26<sup>th</sup> January at the National Health Commission press



conference (http://outbreaknewstoday.com/china-novel-coronavirus-national-health-commission-press-conference-transcript-27680/). He outlined a three point Government strategy to deal with the Coronavirus epidemic centred on "organizing experts to print out the guidelines for diagnosis and treatment, emergency monitoring, epidemiological investigation and disposal, sampling technology and other programs, and organizing research and development of diagnosis."

#### **Chinese National Coronavirus Protocol:**

Central to the national China Government strategy are "the Guidelines, Diagnosis and Treatment Protocol for Novel Coronavirus-Infected Pneumonia (5th Edition, edited by China National Health Commission and National Administration of TCM)" (https://mp.weixin.qq.com/s/GP-jcmlHOctVkkiWSBstrg), which includes under section VIII Treatment;

"(III) Treatment for Severe and Critically Severe Patients

3. Circulation Support: Based on Adequate Fluid Resuscitation, improve microcirculation, use vasoactives, and conduct **hemodynamic monitoring** when necessary."

This protocol was released on the 5<sup>th</sup> of February and is currently being implemented in hospitals across China. The USCOM 1A haemodynamic monitor has over 300 peer reviewed papers and clinical trials, many on applications in infectious diseases and is widely installed in many Chinese hospitals. While non-USCOM 1A haemodynamic monitors are used at some sites in China, most are limited in accuracy, are invasive or require a single device per patient, all features which limit their utility for monitoring tens of thousands of patients infected by the coronavirus. The optimal choice of haemodynamic monitoring devices is critical, and poor, slow or inaccurate devices may result in fatal patient outcomes.

## Coronavirus, Pneumonia and Sepsis:

Severe sepsis is a leading cause of death globally and the most common cause of death among critically ill patients in non-coronary intensive care units (ICU). Sepsis from respiratory tract infections, particularly pneumonia (such as coronavirus), are the most common (~40%), and associated with the highest mortality (22%). Patients ultimately die of cardiovascular and pulmonary failure, so cardiovascular and pulmonary support are the frontline treatments for the disease, particularly in the absence of effective antibiotics or vaccines.

#### **USCOM 1A:**

The USCOM 1A is an accurate and simple to use haemodynamic monitor which provides unique diagnostic and therapeutic information about cardiovascular function, noninvasively within five minutes. The age of reported Coronavirus patients in China varies from neonates, children, pregnant women, adults to elderly people, and the USCOM 1A is the only hemodynamic monitor to provide comprehensive normal reference values and management protocols for all ages and patient groups, allowing individually precise diagnosis and treatment. The USCOM 1A can be widely utilised and moved freely between patients following disinfection, making it ideal for frontline management of epidemic infectious disease where large numbers of patients require rapid and accurate evaluation and treatment. The USCOM 1A is based on highly accurate non-invasive Doppler ultrasound and replaces invasive catheter based monitors.



## **USCOM 1A Regulatory:**

The USCOM 1A received a five-year NMPA approval for sale in China on 30<sup>th</sup> December 2019.

#### **SARS Connection:**

The USCOM 1A was originally fast tracked for China regulatory approval to assist clinicians in the management of SARS, another coronavirus (Uscom ASX announcements 20-4-2004, 4.27pm). The 2019-nCoV is related to SARS but seems to be more contagious.

#### **USCOM 1A in Coronavirus:**

The circulation changes rapidly during serious infections as the body defends against the infection, and patients ultimately die from cardiovascular and pulmonary failure. The USCOM 1A accurately monitors circulation and detects abnormalities, and monitors the effect of appropriate life-saving cardiovascular interventions including fluid, inotropes and vasoactive therapies.

#### **Current installations:**

There are already numerous USCOM 1A devices installed in China, predominantly into ICU departments for the diagnosis and management of infectious diseases. Many will be currently in use to manage Coronavirus patients.

## **Chinese Hospitals:**

There are ~15,000 Hospitals in China, and the Coronavirus has now been reported nationwide. Complying with the National Protocols might require at least one USCOM 1A per Adult (ICU and Emergency Dept), Paediatric (PICU) and Neonatal Intensive Care Unit (NICU) per hospital.

## **New Coronavirus Installations:**

The first USCOM 1A installed specifically to assist with the diagnosis and management of Coronavirus was in the Shandong Provincial Chest Hospital on the 23<sup>rd</sup> January 2020. Uscom has a number of hospital tenders currently under submission, with new tenders continually being raised to equip departments to deal with the epidemic.

## **Uscom Mission:**

As infections become more frequent, more severe, more resistant and more widespread the need for non-invasive, accurate and widely applicable monitoring technologies will increase. Uscom's mission is to develop and deliver accurate science leading cardiovascular and pulmonary technologies to limit the impact of these infections worldwide. The national implementation of the Chinese Government Coronavirus Protocols will assist in this mission long term.

#### **Uscom China:**

Uscom has operated into China and partnered with Chinese universities, academic colleges and hospitals for over 15 years and recently opened a wholly owned Beijing subsidiary. Uscom has appointed an experienced Chinese Director of China Operations, Ms Teresa Guo, and was granted an importation license, a Type II medical device sales license, and employs a national



Chinese operations and support team. Uscom China has actively restructured and expanded its China distribution resulting in increased national reach and an increase in per unit margins. Uscom has also appointed a non-executive Board member, Mr Xianhui Meng, who has Chinese Government administrative experience and was most recently an Executive Director with a large China pharma company with responsibilities in Government relations. Uscom currently has 2 additional suites of cardiovascular and pulmonary medical devices progressing through Chinese NMPA regulatory approval which are planned to create new and discrete business streams by the end of 2020.

#### Adjunct Associate Professor Rob Phillips:

Rob Phillips, the founder of Uscom Limited and inventor of the USCOM 1A is an Adjunct Associate Professor at The University of Queensland in the Department of Medicine. He has lectured extensively in China particularly on haemodynamic monitoring and management of infectious diseases over the last fifteen years, and holds a visiting professorial position with the Jining University Medical School, Jining University, Jining, Shandong, China.

## **Expanding Manufacturing to Meet Demand:**

Uscom is closely monitoring the growing demand from China, and based on orders from the first five weeks of 2020 is initially forecasting an increase in H2 manufacturing volumes of 121% from 10 year mean half year manufacturing volumes of 42 (2010-2019). Uscom has a three-point strategy to meet the increasing demand for USCOM 1A.

- 1. Increase Australian in-house manufacturing (already implemented)
- 2. Outsource pre-assembly to Australian contract manufacturers (implementation pending)
- 3. Develop Chinese manufacturing operations (Dependent on demand)

The Uscom manufacturing strategy will depend on the scale of the demand increases and the regulatory consequences of the changes.

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. The USCOM 1A provides vital guidance for optimising management of infectious diseases and the administration of fluid, inotropes and vasoactive therapies in critical care monitoring. The BP+ SpiroSonic devices improve diagnosis and management of hypertension, heart failure, asthma, COPD and sleep disorders in the clinical and home care environments.

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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

## **Uscom Contacts**

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