



18 June 2019

CLINICAL TRIAL UPDATE

Respiri limited (ASX: RSH) (“Respiri” or the “Company”) is pleased to report the first clinical study to demonstrate the clinical relevance of the company’s digital wheeze detection technology is in progress with wheezo™ performing to expectations.

The aim of this first study is to compare and correlate wheezo’s acoustic respiratory monitoring technology and wheeze rate as a measurement of wheeze severity in patients with clinician assessment of wheeze severity, including chest auscultation using a stethoscope. It is the first of two short studies designed to provide further evidence for the company’s healthcare professional (HCP) education program and to provide the evidence required to achieve endorsement by asthma bodies such as Asthma Australia, Asthma UK and the respiratory community.

As announced on 29 April 2019, when ethics approval was received, **Professor Francis Thien**, Director of Respiratory Medicine at Eastern Health is the Principal Investigator recruiting patients upon admission to Box Hill Hospital with an exacerbation of asthma or COPD, causing wheeze. Recruitment is ongoing, and we have amended the protocol to include emergency patients to increase the numbers of subjects with severe disease and take the opportunity to test the technology in the ED setting. While we await approval for the amendment, we continue to record the wheeze rate of every patient who is admitted to the hospital presenting with wheeze upon admission and again, upon discharge.

Whilst Respiri will not be providing a preliminary analysis of the data prior to publication of the abstract, we are pleased to report the effectiveness of the noise cancellation feature implemented in the new product design with the addition of the second microphone for background noise. **wheezo™ and its technology upgrade to better detect and measure wheeze rate is working without fail in the challenging hospital environment.**

Australian Medical & Scientific Advisory Board and Second Short Study

The second short study aims to correlate wheeze rate with the lung function parameters measured in Spirometry, Multiple Breath Washout (MBW) and Forced Oscillation Technique (FOT).

The protocol is in the final planning phase under the guidance of Professor Bruce Thompson and Professor Frank Thien whose expertise is enhanced by that of **Professor Sarath Ranganathan** and **Professor Greg King** who have joined Respiri’s Australian Medical and Scientific Advisory Board.



Prof Sarath Ranganathan



Prof Greg King

Professor Ranganathan is Director of Respiratory Medicine at the Royal Children's Hospital, Head of the Department of Paediatrics at the University of Melbourne and respiratory group leader at the Murdoch Children's Research Institute. Globally recognised as an expert in clinical respiratory physiology and early lung disease, Professor Ranganathan is a fellow of the American Thoracic Society, the world's leading organisation for research, clinical care and public health in respiratory disease, crucial illness and sleep disorders.

Professor Greg King is the research leader of the Airway Physiology and Imaging Group at the Woolcock Institute of Medical Research and staff specialist in the Department of Respiratory Medicine at Royal North Shore Hospital, where he directs the asthma service and is the Medical Director of the Respiratory Investigation Unit. He is Professor of the Northern Clinical School of the University of Sydney and Practitioner Fellow of the National Health and Medical Research Council.

Respiri's goal is to publish in prestigious, high impact respiratory journals once the analysis of all the data from the full sample for each of the studies is complete. The receipt of the CE Mark and subsequent TGA approval clearing wheezo™ for sale is independent of these clinical studies which will be completed prior to launch.

UK Medical & Scientific Advisory Board Study Planning Meeting

Next month, the UK Medical and Scientific Advisory Board will come together in a follow-up meeting to familiarise themselves with the completed wheezo™ breath sensor and app, review the Australian studies and plan for local studies ahead of launch in the UK. Further, the studies in the UK are intended to provide the clinical evidence for wheezometry to be included in NICE (National Institute for Health and Care Excellence) guidelines as standard care and therefore, for adoption in the NHS. As is the case in Australia, Respiri is very proud to have attracted some of the most respected leaders in respiratory medicine as supporters of our mission to address an unmet need and improve asthma care.

Experts include Professor Aziz Sheikh OBE, Professor Jonathan Grigg, Professor Anoop Chauhan, Dr Mark Levy, Dr Katy Pike, Dr Paul Seddon, Dr Louise Fleming.

Regulatory process timeline

The critical plastic tuning for medical device biocompatibility compliance has now been finalised and pre-production units are being manufactured at SRX for shipping to the safety and compliance laboratory on Friday 21 June. This testing process takes 12 weeks and upon receipt of the lab report, Respiri will undergo the Stage 2 quality management system (QMS) audit and make its CE submission. Once the submission is received by the Notified Body, the time frame for review and certification is expected to be up to 3 months. The company will make every effort to expedite the assessment process and notes that the quality of wheezo™ is paramount. The remaining pre-production units will be used for stakeholder demonstrations in the UK, India and Australia and further beta testing.

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About Respi Limited

Respi's mission is to help improve quality of life for millions of children and adults around the world and dramatically reduce hospital admissions and the economic burden of asthma. The Company offers sensors, mobile apps and analytics to support respiratory health management. Its world first technology detects wheeze, a typical symptom of asthma, COPD and respiratory disease to provide an objective measure of airway limitation. Respi's innovative platform provides personalised feedback and education based on the user's data and enables the sharing of that data with caregivers and health care providers. Respi Limited's operations are based in Melbourne, Australia.

Forward Looking Statements

Certain statements made in this announcement are forward-looking statements. These forward looking statements are not historical facts but rather are based on Respi's current expectations, estimates and projections about the industry in which Respi operates, and its beliefs and assumptions. Words such as "anticipates," "expects," "intends," "plans," "believes," "seeks," "estimates," "guidance" and similar expressions are intended to identify forward looking statements and should be considered an at-risk statement. Such statements are subject to certain risks and uncertainties, particularly those risks or uncertainties inherent in the process of developing technology and in the endeavour of building a business around such products and services. These statements are not guarantees of future performance and are subject to known and unknown risks, uncertainties and other factors, some of which are beyond the control of Respi, are difficult to predict and could cause actual results to differ materially from those expressed or forecasted in the forward looking statements. Respi cautions shareholders and prospective shareholders not to place undue reliance on these forward looking statements, which reflect the view of Respi only as of the date of this release. The forward looking statements made in this announcement relate only to events as of the date on which the statements are made. Respi will not undertake any obligation to release publicly any revisions or updates to these forward looking statements to reflect events, circumstances or unanticipated events occurring after the date of this announcement except as required by law or by any appropriate regulatory authority.