ASX ANNOUNCEMENT

1 September 2020

wheezo™ Demonstrates Very Promising Results for the Detection of Wheeze in a Clinical Study

Respiri Limited (ASX:RSH)("Respiri" or the "Company"), an eHealth SaaS Company supporting respiratory health management, today announces the preliminary results of a clinical study comparing wheezo™ to the gold standard clinician based stethoscope measurement of wheeze in asthma and chronic obstructive pulmonary disease (COPD) patients in a stable condition in the emergency department or admitted to hospital with an exacerbation of airway disease. A total of 56 patients participated in the study (55 eligible for data analysis), with 114 recordings taken. A total of 11 physicians participated in the study, which was unblinded and non-randomised by design.

The Principal Investigators were Professor Frank Thien, Director of the Department of Respiratory Medicine at Eastern Health, Box Hill Hospital, Monash University and Professor Bruce Thompson of Swinburne University, Melbourne. The aim of the study was to use wheezo™ to assess wheeze severity in patients admitted with an exacerbation of airway disease with clinically detectable wheeze, and correlate it with physician's assessment of wheeze severity using a stethoscope. The device calculated the duration of wheeze in 30 seconds of breath sound recording while a clinician scored the severity of wheeze on a scale of 0 through 10.

The study results show that the wheeze rate measured by wheezo™ (previous algorithm) at the trachea (windpipe) had a true positive (sensitivity) of 74% and correctly detected no wheeze (a true negative) of 83% (specificity). The Cohen's kappa coefficient was calculated as 0.46, which means "moderate agreement" between wheezo and physicians in detecting wheeze.

The study data was reanalysed by the Company in this report and a new and improved proprietary algorithm developed. The wheezo device when compared to the physician assessment of the chest and trachea was able to correctly detect a true positive (sensitivity) in 81% of cases and correctly detect no wheeze (a true negative) in 79% of cases (specificity). It is recognised that Physician assessment of wheeze is subjective and when adjusted for two physicians that showed significant disagreement to retrospective breathing recordings wheeze assessment, the sensitivity of the device increased to 89%. Further, Cohen's kappa coefficient also improved from 0.51 (moderate agreement) to 0.64 in the latter population of physicians demonstrating substantial agreement. This new algorithm will be used to test the device performance in a new clinical study.

Further details of the preliminary study data are provided in **Appendix 1**.

Mr Marjan Mikel, CEO & Managing Director of Respiri said "The detection of wheeze at such high levels of sensitivity and specificity as shown by our latest algorithm when benchmarked against a physical assessment undertaken by a trained clinician using a stethoscope, highlights the potential of our device to provide accurate, real-time measurements of wheeze in patients outside of the clinical setting where monitoring of the disease is paramount. Given this significant advance in algorithm accuracy, we are currently in the process of filing a Patent Cooperation Treaty (PCT) to protect our company asset."

Mr Mikel continued "For clinicians, this study represents an important step in the ongoing validation of our device and proprietary algorithm as for the first time we have shown a high degree of accuracy to the gold standard measurement of wheeze. Accordingly, patient self-assessment using wheezo and the real-time data it provides will confer a high degree of confidence in wheeze measurement and monitoring to their treating doctor outside of the clinic, which is an important consideration as Respiri moves forward with its commercial launch in the fourth quarter of calendar year 2020."

An Australian survey reported that uncontrolled asthma in the community was as high as 45%, with frequent hospital admissions and unscheduled medical visits. Despite this, just 50% of patients had been seen by a general practitioner within the previous year, and only 10% had been reviewed by a specialist[1]. In one multinational survey, 90% of patients self-rated their asthma as well controlled, but of these only 18% were indeed controlled based on the definition in the Global Initiative for Asthma guideline[2]. The market need for a device that effectively monitors wheeze in an ambulatory setting that correlates with physician-based measures therefore remains high, which drives Respiri's development and commercial plans. In addition to the algorithmic wheeze analysis the breathing sound files are also stored in the cloud and can be reviewed and analysed by clinicians once permission is granted by the patient,

The study also demonstrated the subjective nature of physician rating wheeze severity. Study investigators have developed a novel approach to minimising this subjectivity by visually and audibly objectively scoring the breathing recordings. Although more work is required with this approach, (a similar approach is used in the standardised assessment of sleep apnea diagnostics tests) this could provide a standardisation of wheeze severity measurement which is lacking today. A clinical development road map is already in development to accelerate the refinement of wheeze scoring.

The Company and its study investigators intend to submit the results of the study to a leading respiratory scientific journal for publication prior to the end of the 2020 calendar year.

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This ASX announcement dated 1 September 2020 has been authorised for release by the Board of Directors of Respiri Limited.

About Respiri Limited

Respiri is an e-Health SaaS company supporting 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. The only platform of its kind, the flagship wheezo product employs machine learning to provide personalised feedback and education based on the user's personal health data correlated with environmental factors, and enables the sharing of that data, anytime, anywhere with caregivers, physicians and other health care professionals.

Respiri's mission is to help improve quality of life for hundreds of millions of children and adults around the world and dramatically reduce hospital admissions and the economic burden of asthma. Respiri Limited's operations are based in Melbourne, Australia.

For additional information about Respiri and its products, please visit www.respiri.co

[1] Reddel HK, Sawyer SM, Everett PW, et al. Asthma control in Australia: a cross-sectional web-based survey in a nationally representative population. *Med J Aust* 2015; 202: 492-496.

[2] Price D, David-Wang A, Cho SH, et al. Time for a new language for asthma control: results from REALISE Asia. *J Asthma Allergy* 2015; 8: 93-103.

About wheezo

Developed in Australia, with the support of respiratory specialists and other healthcare professionals, the innovative wheezo device records wheeze, and the eHealth App assists patients with managing their asthma by tracking symptoms, triggers, medication use and geo-specific weather conditions. The platform has been designed to extend asthma management beyond the clinic and make it easy to share information with doctors and make appropriate adjustments to asthma action plans. Better active management may lead to better outcomes and improved quality of life for the asthma patient.

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 Respiri current expectations, estimates and projections about the industry in which Respiri 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 Respiri, are difficult to predict and could cause actual results to differ materially from those expressed or forecasted in the forward looking statements. Respiri cautions shareholders and prospective shareholders not to place undue reliance on these forward looking statements, which reflect the view of Respiri 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. Respiri 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.

Appendix 1 –Details of the wheezo Clinical Study

Study Title: Assessing the clinical utility of an electronic wheeze detection tool to monitor wheeze severity and resolution in patients admitted with an exacerbation of airway disease

Short Title: Wheeze monitor in exacerbation of airway diseases

Principal Investigator: Prof. Frank Thien, MD FRACP FCCP

Location: Box Hill Hospital and Maroondah Hospital

Design:

Inclusion criteria:

- Patients admitted to hospital with an exacerbation of airway disease causing wheeze (asthma and COPD) or in stable condition in the emergency department
- Ability to give written consent for measurement of wheeze with the electronic wheeze detection tool as part of routine clinical care.
- Age 18 and older

Exclusion criteria:

Other condition(s) which in the clinicians' assessment is the predominant cause of wheeze such as:

- bronchiectasis
- congestive cardiac failure
- large airway obstruction (e.g. tracheal tumors and laryngeal dyskinesia)

Data Collection and Analysis:

The wheeze severity by the electronic device and clinician assessment will be compared and correlated. The degree of correlation among the clinicians and the electronic wheeze detection device will be evaluated using the Kappa coefficient. The correlation analysis will be repeated for different threshold values of wheeze rate.

Protocol:

1. Patients in a stable condition in the emergency department or admitted to hospital with an exacerbation of airway disease will be verbally introduced to the study and provided with a participant information and consent form. Signed consent for the use of the electronic wheeze detection device will be obtained from the patients who are willing to participate

2. The electronic wheeze detection device is held at the base of the neck and records wheeze while the patient breaths normally for 30 seconds giving a "WheezeRate". The Wheeze rate is calculated as the breathing time with wheeze over 30 seconds of entire recording of breath sounds.

3. The clinicians perform their usual clinical assessments (clinical examination and chest auscultation with a stethoscope) and record their clinical findings including a severity of wheeze with a visual analogue score. The clinician scored the severity of wheeze on a scale of 0 through 10.

4. The assessment is repeated at the end of admission or prior to discharge from ED.

Preliminary Results:

Results from the first generation of algorithm used in patients versus clinician assessed measures is shown below. In each study, the physician was asked to score their assessment of auscultation on chest and trachea separately. Max refers to highest score by the physicians on chest and trachea measurements taken with a stethoscope.

Classification results using threshold of 3 for wheeze rate and 1 for the physician's score. The wheeze rate values are rounded in this calculation to be consistent with the way it is reported in the app.

	wheeze rate vs chest	wheeze rate vs trachea	wheeze rate vs max (chest, trachea)
Sensitivity	74%	77%	74%
Specificity	83%	75%	95%

A second improved algorithm that sought to distinguish between loud wheeze and speech coupled with the implementation of a different signal processing technique to detect wheeze. The new algorithm takes into account the amplitude of the background and trachea signal for noise cancellation. The new algorithm is more sensitive to detect features in the sound that is similar to wheeze. Accordingly, the higher threshold was chosen by including a data set of non-wheeze breath sounds in the analysis. The results are shown below. Cohen's kappa coefficient is calculated as 0.51 which shows moderate agreement.

Classification results of 114 recordings from 55 patients. The threshold of 5 for wheeze rate and 1 for the physician's score. The wheeze rate values are rounded in this calculation to be consistent with the way it is reported in the app.

	wheeze rate vs chest	wheeze rate vs trachea	wheeze rate vs max (chest, trachea)
Sensitivity	81%	83%	80%
Specificity	79%	67%	90%

Reviewing the studies, showed significant disagreement with two of the physicians on wheeze scores for some study subjects. Excluding those subjects, the remaining subgroup of 41 patients showed a significant improvement in performance as shown below. Cohen's kappa coefficient is calculated as 0.64 which shows substantial agreement.

Classification results using the subset of data (41 patients, 89 studies) excluding two physicians (Dr. #8 and Dr. #10). The threshold of 5 for wheeze rate and 1 for the physician's score. The wheeze rate values are rounded in this calculation to be consistent with the way it is reported in the app.

	wheeze rate vs chest	wheeze rate vs trachea	wheeze rate vs max (chest, trachea)
Sensitivity	89%	86%	87%
Specificity	79%	60%	93%