RESPIRI

ASX ANNOUNCEMENT

3 June 2021

Respiri continues to progress positively towards securing RPM CPT Reimbursement and addresses statements made by Adherium which Respiri believe are inaccurate.

Respiri Limited (ASX:RSH)("Respiri" or the "Company"), an eHealth SaaS company supporting respiratory health management announces that following its receipt of US Food and Drug Administration (FDA) 510(k) clearance for wheezo® in March 2021, the Company commissioned an independent expert evaluation of its wheezo® device (and associated App) to assess its eligibility to qualify for Remote Patient Monitoring (RPM) Current Procedural Terminology (CPT) code reimbursement – a significant insurance reimbursement regime which exists in the US market.

The expert, based in the USA, is an experienced advisor to US CPT coding committees and MACRA task forces. The Medicare Access and CHIP Reauthorization Act (MACRA) is a law that governs how the US federal government pays / reimburses physicians.

In summary, the expert concluded that wheezo® analyses breath sounds for the presence of a wheeze and that in the expert's opinion, breath sounds and wheezing are physiologic parameters.

Respiri is now in discussions with several insurers, Chronic Care and Disease Management Companies (organisations that specialise in promoting and supplying medical devices and solutions to Health Care Professionals, including devices which are CPT code approved) in the US market to secure reimbursement arrangements and identify business partners. Securing reimbursement arrangements/agreements with insurers, Chronic Care and Disease Management Companies is the final step for Respiri to be able to receive revenue via CPT code reimbursement. The Company will keep the market informed of developments regarding these initiatives.

Clarification of statements made by Adherium

Adherium makes certain statements in its ASX Announcement of 10 May 2021, "*Adherium Directors' Statement re Takeover*" (**ADR Announcement**) which are qualified by its awareness. In Respiri's opinion, such statements have the potential to be misleading and/or inaccurate.

Respiri provides the following information to address Adherium's knowledge and to ensure the market remains appropriately informed.

Adherium statement	Respiri response
"Respiri has only one sensor, for which currently to Adherium's knowledge there are no publicly available independent clinical trial results, and nor is it supported by any independently conducted clinical trial publications in peer reviewed journals…"	Respiri has been developing respiratory devices (and associated algorithms) to measure breathing sounds and wheeze for over 20 years, improving these technologies significantly over this period. This work has culminated in the development of wheezo®, which has built on and improved previous device iterations, including Respiri's first FDA approved device, PulmoTrack (approved in 1998). The significance of measuring breath sounds and wheeze has been studied for over 20 years and has been published in more than 10 peer reviewed medical journal publications (examples detailed below). Further, Respiri was required to submit its latest clinical data analyses in its FDA 510(k) submission. This new wheezo® study data was reviewed by the FDA Reviewer Team (one of the most rigorous regulatory bodies in the world) and compared to a peer reviewed, well-studied and documented, FDA-approved predicate device (in

	wheezo's case, the extensively studied Respiri devices). The FDA determined that wheezo with its current data, profile and clinical applications is at least equivalent to this other well-studied predicate device and approved wheezo® for use in the USA. This standard practice for 510(k) submissions and a different approved regulatory pathway made available by the FDA. Adherium, understandably is pursuing the same 510(k) submission, for their new Haille sensor to expedite approval and minimise unnecessary expenditure. As an eHealth MedTech company Respiri has several additional KOL-driven and designed clinical trials going through ethics and other approvals designed to continue to demonstrate the clinical utility of wheezo® in providing patients and their carers (Health Care Professionals included) care beyond the clinical driven health outcomes benefits and these will be the subject of future announcements.

Adherium statement	Respiri response
"The clinical significance of measuring wheeze in the treatment of Asthma and COPD and whether this would qualify for reimbursement, in particular in the US, has currently to Adherium's knowledge not been independently demonstrated or verified."	Respiri asserts, that in its opinion, Adherium's statement is inaccurate and very narrowly focussed – wheezo® does not only measure wheeze, but it also measures and records breath sounds, which are each considered to be physiologic parameters, an assertion which is supported by independent expert evaluation.

The importance of measuring wheeze

The current global gold standards for diagnosing asthma severity comes in the form of clinically validated questionnaires, Asthma Control Questionnaire (ACQ) and the Asthma Control Test (ACT). These questionnaires assess patient's symptoms/conditions as the current method of asthma severity diagnosis. These symptoms/conditions resulting from their asthma include:

- How often the patient wakes at night?
- Symptom severity when the patient wakes?
- How limited were patients in conducting their daily activities?
- How much shortness of breath did the patient experience; and
- How much of the time did the patient wheeze?

Further, various international peak asthma bodies recommend tracking and measuring wheeze. For example, the Asthma Australia handbook of asthma recommends that breathing sounds described by parents/carers as 'wheezing' be confirmed as actual wheeze, and that health care professionals ask parents/carers to make an audio or video recording of noisy breathing for this purpose.

Recommendations from GINA (Global Initiative for Asthma) guidelines: " Does your child have wheezing?" involve use of a video questionnaire or asking a parent to record a breathing episode on a smartphone if available. As not all wheeze is audible, there are limitations to these recommendations. Moreover, breath sound and wheeze recordings depend on the characteristics of the smartphone microphone and the placement of the phone on the chest, back or trachea.

The need for a specialised, sensitive, and consistent alternative to a smartphone microphone is evident. wheezo® is a medical device that reliably records breath sounds and provides an objective measurement of wheeze.

Further wheeze and other asthma symptoms and their relevance to asthma diagnosis and management have been extensively studied and published in peer reviewed journals over a very long period and continue to be studied.
In light of the above, Respiri looks forward to Adherium correcting its previous statements above in a timely manner.

Cited medical publications.

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This ASX announcement dated 3 June 2021 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. wheezo®, Respiri's innovative technology, comprises an eHealth app combined with a simple, easy to use, handheld device. wheezo® is the first smart device to help improve asthma management by monitoring wheeze and documenting symptoms, signs, triggers, weather conditions and medication use. The asthma management platform also facilitates the sharing of data 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

About wheezo®

Developed in Australia, with the support of respiratory specialists and other healthcare professionals, the innovative wheezo® device analyses breath sounds for 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.