ASX ANNOUNCEMENT

7 October 2019

SHAREHOLDER UPDATE

Respiri Limited (ASX:RSH) ("Respiri" or the "Company") is pleased to provide an update on its core activities for the launch of wheezo®, a world-first in symptom monitoring for asthma.

CE Mark Submission

Respiri is pleased to announce that wheezo® has passed all safety and compliance tests with an independent laboratory report expected to confirm this due in the coming week. As previously reported to shareholders, the regulatory process experienced delay due to soft plastics biocompatibility challenges and finalisation of the wheezo® breath sensor design. Once this issue was resolved by Respiri's technology partner, Grey Innovation, which it resolved through extensive testing of various materials sourced from overseas, the safety and compliance testing process by an independent laboratory could commence.

The CE mark is a conformity mark and seen as a declaration by the manufacturer that the product meets all the appropriate provisions of the relevant legislation including those related to safety.

Before placing wheezo® on the European market, Respiri (as the manufacturer) has an obligation to produce certain technical documentation including the laboratory report expected as described above, providing evidence of conformity with the Medical Devices Directive (**MDD**) 93/42/EEC. For shareholders' benefit, this process is set out in some detail below.

The technical file represents the entirety of the documents describing wheezo®. It covers design, manufacture and intended operation of the product. Data must be provided that is sufficient to demonstrate that wheezo® will perform safely and achieve the stated performance claims for its intended use.

Following receipt of the expected laboratory report, the required wheezo® technical file is intended to be completed and provided for review by the Notified Body in mid-October. The role of the Notified Body is to conduct the conformity assessment against the relevant sections of the applicable MDD. The assessment involves review of the technical file and an audit of the Company's fully functional Quality Management System (**QMS**) for ISO 13485 certification.

Respiri's second audit of its QMS by the Notified Body German auditor is likely to follow two weeks after the submission of the technical file. It is important to note that the accredited authorities in Europe are making the transition from the current MDD to Medical Device Regulation to take effect in May 2020, and as such there is extreme pressure on the Notified Body's resources.

Once the Notified Body has determined that Respiri has conformed to the relevant assessment criteria, Respiri expects that it will issue an EC certificate to show that wheezo® meets the applicable requirements, in which event Respiri will be required to sign a Declaration

of Conformity and apply the CE mark with the Notified Body number. wheezo® may then be placed on the market in the European Economic Area (EEA). The CE mark will also allow immediate sales in India. The Company will continue to provide the market with any material updates on the progress of the EC certificate following submission. We expect the Notified Body review process and CE approval to take up to twelve weeks from submission, allowing sales of wheezo® from February 2020.

Once CE approval has been obtained, a TGA submission will be made for ARTG (Australian Register of Therapeutic Goods) listing.

Clinical Studies

The primary purpose of the clinical studies being undertaken at the instruction of Respiri is to obtain and be able to provide further evidence to support the Healthcare Professional (**HCP**) wheezo® education program and to garner endorsement of wheezo® from asthma bodies such as Asthma Australia. It is expected that favourable clinical studies will strengthen Respiri's B2C sales campaign. The studies are not a pre-requisite for the Company's CE submission, which is in the final stage.

Professor Frank Thien, Director of Respiratory Medicine at Eastern Health is the Principal Investigator on the first study to demonstrate the clinical relevance of the technology. Professor Thien, supported by his team of doctors and Dr Samaneh Sarraf, Respiri's CRO, are now close to completing the data collection. The protocol involves the recruitment of patients on admission to Box Hill Hospital who are suffering from an exacerbation of asthma or COPD causing wheeze. Data is also being collected from every asthma or COPD patient who presents at the Emergency Department of Box Hill Hospital and the Company has recently received permission to include patients at Maroondah Hospital.

A positive for people living with asthma, the relevant patient numbers under the clinical study were surprisingly low during winter with only 40% of required recordings completed. However, with pollen season commencing in Melbourne (as it generally does across October and November), it is expected that a greater number of patients will present at hospitals with exacerbation of asthma in the next few weeks, which is expected to provide sufficient data for Professor Thien and his team to complete the required data collection by the end of November. Professor Bruce Thompson, Respiri director and Chairman of its Medical and Scientific Advisory Board, is delighted with the analysis of results thus far, which have demonstrated a high degree of accuracy, specificity and sensitivity.

The second study on the correlation of wheeze rate with the lung function parameters measured in Spirometry, Multiple Breath Washout (MBW) and Forced Oscillation Technique (FOT) will also be completed, along with the first study, to coincide with CE mark approval and the sales campaign for wheezo®.

Manufacturing

Respiri has ordered a pilot build of 500 wheezo® to be produced at SRX Global's Dandenong plant with the objective of optimising the manufacturing process in readiness for product orders. SRX Global is currently in the component procurement cycle and is expected to deliver the order of 500 units by the end of December.

20 pre-production wheezo® units are also being shipped to JV partner, MedAchievers, in New Delhi this week, with another 30 units expected to follow soon after. The units are to be used in pre-market clinical studies that are aimed at replicating the Australian protocol at major hospitals in India as announced by Respiri on 20 September 2019.

The Company looks forward to being in a position to provide further updates to shareholders on the progress of the core activities and ultimately, to the first sales of wheezo® described in this announcement.

---End---

Contact:
Mario Gattino
CEO & Director
+61 9653 9160

About Respiri Limited

Respiri'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. Respiri'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. Respiri 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 Respiri's 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.