



RESPIRI PROGRESSES CE MARK REGISTRATION

Respiri Limited (ASX:RSH) is pleased to announce an update on progress of the go-to-market strategy for wheezo™ .

CE Mark | Stage 1 Audit Complete

On 21 February, 2019, Respiri announced some of the essential steps needed to ensure wheezo meets all regulatory and quality requirements and receives the CE mark for launch in the initial target markets of UK, Australia and Singapore.

The first step towards the CE mark is certification to ISO 13485, the internationally recognised quality standard. This certification requires Respiri's QMS to pass an independent 'Notified Body' Conformity Assessment.

On 27 February, the Company successfully underwent the first stage of the assessment conducted by Notified Body, DQS, in which its Quality System was reviewed. This review determined Respiri's readiness for the stage 2 audit.

The stage 2 audit is expected to take place during April/May while independent safety and compliance testing is being conducted. Upon receipt of the safety and compliance lab report, the technical files will be finalised for submission. Consistent with previous advice, the duration of the last stage of the CE marking process where the Notified Body determines if Respiri has conformed to the relevant assessment criteria and issues a CE certificate, can range from one to three months. Respiri will then sign a Declaration of Conformity and the CE mark will be applied to the wheezo product, enabling immediate sale in the UK with TGA approval in Australia and HSA in Singapore to follow approximately six weeks later.

Respiri, Eastern Health and Swinburne University join forces for first Clinical Study

As recently advised, short term clinical studies are required to achieve critical endorsement of wheezo by respiratory medicine's key opinion leaders, GPs and asthma bodies such as Asthma UK and Asthma Australia. The first study to demonstrate that wheezo hears what a doctor hears with a stethoscope and to determine the relevance of the wheeze rate value is awaiting ethics committee approval and will start immediately led by Professor Bruce Thompson, Dean of the School of Health Sciences, Swinburne University and Professor Francis Thien, Director of Respiratory Medicine, Eastern Health. The second short study protocol, which is slightly more complex, will be submitted for ethics approval shortly.

Exhibition at Australasia's premier Respiratory Meeting

The Annual Scientific Meeting of The Australia and New Zealand Society of Respiratory Science and The Thoracic Society of Australia and New Zealand will take place on the Gold Coast from 28 March to 2 April 2019. It presents an invaluable opportunity for Respiro to introduce wheezo as the answer to an unmet need in asthma symptom monitoring to a captive audience of key opinion leaders, the multinational brands in medical devices and Big Pharma companies. All key participants in Australasian respiratory medicine will be in attendance and be exposed to the Respiro solution.

Conference Call Scheduled

CEO Mario Gattino will be joined by key members of the Respiro development team for a shareholder conference call on Thursday 28 March at 11.00am AEDT. Details of how to participate will follow early next week.



--END--

Contact:

Gerry Bullon
Investor Relations
+61 418 106 675

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.