

ASX ANNOUNCEMENT

10 December 2019

wheezo® Approved for Sale with CE Mark & TGA registration, identifies potential device manufacturer and enters into clinical study agreement with Swinburne University, Melbourne.

Respiri Limited (ASX:RSH) (“Respiri” or the “Company”) is pleased to announce that ahead of forecast, it has achieved a significant milestone with CE Mark and TGA approval to list wheezo® in the Australian Therapeutics Goods Register (ARTG). wheezo® is the world’s first digital wheeze monitoring solution, comprising sensor, smartphone application and state-of-the-art platform, to help people with respiratory disease such as asthma better manage their condition.

As previously announced, the Company submitted the Technical File representing the entirety of the documents describing wheezo® to demonstrate that the product will perform safely and achieve the stated performance claims for its intended use. As part of the process, Respiri also undertook the second audit of its Quality Management System to achieve ISO 13485 certification required for medical device manufacturers.

The review process resulted in a re-classification of wheezo® to allow immediate application of the CE Mark and clearance for sales in the European Union (EU) member countries along with immediate approval for listing in the ARTG. There are more than 40 million and almost 3 million asthma sufferers in the EU and Australia respectively, who today cannot effectively monitor their condition on a daily basis. wheezo® will provide them with an effective ambulatory tool to help better manage their condition every day.

“The CE Mark and TGA clearance is a major accomplishment for Respiri as the submission required rigorous regulatory review against high clinical and safety standards,” said Mr Nicholas Smedley, Chairman of Respiri. “With this regulatory step completed, we are now at the point of commercialisation, with focus on our go to market strategy to make this innovative monitoring solution available to people with asthma as soon as possible.”

Further, Respiri is pleased to announce that it has identified a suitably credentialed manufacturing partner operating out of Malaysia for wheezo® production. “We are confident of finalising an agreement with our partners in Malaysia in the New Year”, said Marjan Mikel, Respiri CEO.

Respiri has also entered into a clinical study agreement with Swinburne University, Melbourne, that examines the measurement of wheeze to determine small airway function (asthma). This study is required to correlate wheeze rates against current standard hospital/physician used asthma measures such as Forced Oscillation Technique (FOT) and Multiple Breath Washout (MBW). This clinical trial will be completed by April 2020. This is required prior to commercialising wheezo® as it will provide evidence to physicians that wheezo® is an accurate ambulatory monitoring tool for asthma. “Once we have this, we will

be able to approach potential big pharma partners to help us introduce wheezo® to physicians who can then recommend wheezo® to their patients”, said Mr Mikel.

The Company will have the first 500 pilot batch completed next month to be used with clinicians and patients and is also completing the premium features of the wheezo® application with the intent to deliver the global asthma population with the best respiratory management platform in the marketplace.

All these milestones are to be delivered in a timely basis and they keep the Company on track to commercialise the wheezo® in Q4 2020.

Respiri looks forward to providing shareholders with further updates as wheezo® commercialisation efforts are confirmed and delivered.

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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.