

**ASX ANNOUNCEMENT**

30 January 2020

**FDA application - update**

Melbourne, Australia: 30 January 2020: Respiri Limited (ASX: RSH), a medical device and e-Health SaaS company would like to update investors on the nature of its new FDA submission.

The company plans to lodge a 510(k) regulatory submission with the US Food & Drug Administration (FDA). A 510(k) submission is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective as the predicate device.

Submissions can be cleared in 3 months but generally the timeframe is closer to 6 months. Respiri is allowing 9 months from lodgement in February 2020 so the company is expecting to receive clearance from the FDA by the end of November 2020.

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## About Respi Limited

Respi 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.

Respi'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. 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.