Positive engagement with US FDA following SleepCheck Pre-Submission meeting

- **Meeting provided ResApp with a clear path to gain regulatory approval for SleepCheck use in the US**
- **SleepCheck is ResApp's direct-to-consumer sleep apnoea screening application**
- **ResApp to pursue 510(k) clearance – with a US human factors study to commence at the beginning of Q3 FY2021 followed by a formal submission lodged shortly thereafter**
- **FDA approval would unlock a substantial market – 42m Americans suffer from sleep disorder breathing leading to an economic impact of US$150Bn[i]**

Brisbane, Australia, 24 November 2020 – ResApp Health Limited (ASX: RAP), a leading digital health company developing smartphone applications for the diagnosis and management of respiratory disease, is pleased to provide the following update on the Company's recent meeting with the United States (US) Food and Drug Administration (FDA) regarding the clearance of its mobile medical application SleepCheck for use in the US.

SleepCheck is ResApp's easy to use, direct-to-consumer mobile medical application that uses clinically accurate algorithms to assess a person's risk of obstructive sleep apnoea by analysing breathing and snoring sounds during sleep. It requires no accessories or hardware other than a smartphone to make an assessment.

The company advises that positive engagement with the FDA has defined a clear path towards gaining regulatory approval. ResApp will pursue a 510(k)[ii] regulatory pathway for SleepCheck, initially as a prescription only (Rx only) device. The 510(k) approach is the fastest route to market and leverages a prior 510(k) clearance granted for a predicate device.

The company will commence a human factors study in the US at the beginning of Q3 FY2021. A human factors study employs representative users to assess the product user interface design. Human factors studies only require a minimum of 15 representative users and are shorter and considerably cheaper than clinical studies. ResApp has successfully carried out similar studies for SleepCheck in Australia.

The lodgement of a 510(k) submission is expected to occur by the end of Q3 FY2021, with a decision from the FDA anticipated 90 days thereafter.

Should the company be successful in attaining 510(k) clearance, SleepCheck Rx would be made available to consumers through a direct-to-consumer telemedicine visit. Healthcare providers would conduct a virtual consultation and prescribe SleepCheck to potential sleep apnoea

sufferers, providing a specific code allowing them to download SleepCheck Rx from the Apple or Google Play store.

ResApp also received advice on the requirements to progress an over-the-counter (OTC) approval. The FDA stated that this process would entail additional clinical and human factors studies due to the lack of an FDA cleared OTC predicate device. To support a potential OTC approval, ResApp will commence a US sleep laboratory-based clinical study during Q4 FY2021, in parallel with the 510(k) prescription only process.

FDA clearance would unlock a substantial market opportunity for ResApp. It is estimated that 42m American adults suffer from sleep disordered breathing (SDB)[iii], three in ten men and almost one in five women have sleep apnoea[iv]. It is further estimated that 75% of SDB cases remain undiagnosed[v].

CEO and Managing Director Dr Tony Keating said: *"We are very encouraged by our meeting with the FDA as it provides ResApp with a clear path towards regulatory approval for SleepCheck.*

"We expect to commence the US human factors study in beginning of next year. The study will be short and cost-effective, and will provide the required data for our 510(k) submission. ResApp will also move forward with the US clinical study needed for OTC approval of the product.

"Sleep apnoea is a major health concern in the US, exacerbated by a large number of undiagnosed cases. SleepCheck would provide a low cost, easily accessible screening tool that could potentially reduce the health and economic impact of an increasingly common respiratory condition. We look forward to providing updates to shareholders on the ongoing approval process and the application's broader progress in the coming months."

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About Obstructive Sleep Apnoea

Obstructive sleep apnoea is a serious medical condition characterised by the intermittent partial or entire obstruction of the upper airway, which prevents air from flowing to the lungs for ten seconds or longer during sleep. In some cases, this can happen more than 30 times per hour all night. This causes daytime tiredness, reduced productivity and an impaired immune system, and has been linked to serious complications such as heart disease, hypertension, stroke and type 2 diabetes. Sleep apnoea affects nearly a third of all men, and a fifth of all women.

About ResApp Health Limited

ResApp Health Limited (ASX: RAP) is a leading digital health company developing smartphone applications for the diagnosis and management of the respiratory disease. ResApp's machine learning algorithms use sound to diagnose and measure the severity of respiratory conditions without the need for additional accessories or hardware. ResApp's regulatory-approved and clinically validated products include ResAppDx, a smartphone-based acute respiratory disease diagnostic test for use in telehealth, emergency department and primary care settings; and

SleepCheck, a smartphone application which allows consumers to self-assess their risk of sleep apnoea. Both products are CE Marked in Europe and TGA approved in Australia. For more information, please visit www.resapphealth.com.au.

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This ASX announcement was approved and authorised for release by the board of directors of ResApp Health.

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[i] American Academy of Sleep Medicine and Frost & Sullivan report: "Hidden health crisis costing American billions"
[ii] https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k
[iii] Young et al New Engl J Med 1993
[iv] Peppard et al. Am J Epidemiol 2013
[v] Young et al. Sleep 2008