ResApp receives FDA 510(k) clearance for SleepCheckRx

Brisbane, Australia, 6 July 2022 – ResApp Health Limited (ASX:RAP), a leading digital health company developing smartphone applications for the diagnosis and management of respiratory disease, is pleased to announce that SleepCheckRx has received 510(k) clearance as a prescription-only software-as-a-medical device from the US Food and Drug Administration (FDA). Gaining FDA clearance enables ResApp to commercially market the test in the United States.

SleepCheckRx is an easy to use, at-home sleep test that screens adults for the risk of moderate to severe obstructive sleep apnoea by analysing breathing and snore sounds recorded on an Apple iPhone. It requires no accessories or hardware other than an iPhone to make an assessment. ResApp plans to solicit 510(k) clearance for Android devices in the future.

Sleep apnoea is the most common sleep breathing disorder and affects more than three in every ten men and nearly two in every ten women[1]. Obstructive sleep apnoea is when air stops flowing to the lungs during sleep. The prevalence of sleep apnoea is increasing due to an ageing population and increasing rates of obesity. Studies have shown that up to 80% of people with sleep apnoea are undiagnosed and untreated[2].

SleepCheckRx will be made available to patients via a prescription from their healthcare provider. Patients will be provided with a specific code allowing them to download SleepCheckRx from the App Store, with their results uploaded to a healthcare provider portal.

In an at-home clinical trial of 220 patients comparing SleepCheckRx to simultaneous polysomnography, the SleepCheckRx algorithms correctly identified 89.3% of patients with moderate to severe obstructive sleep apnoea (AHI greater than or equal to 15/hour) and achieved a specificity of 77.6%.

Tony Keating, CEO and Managing Director said: "*We are delighted to have secured FDA clearance for SleepCheckRx. With more than 20 million American adults suffering from sleep apnoea and the majority of those not knowing that they have the condition, this clearance unlocks a significant market opportunity for ResApp. By using SleepCheckRx, physicians will have the opportunity to screen their patients conveniently and quickly for sleep apnoea, helping their patients take the first step to getting treatment.*"

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[1] Peppard et al., Increasing prevalence of sleep-disordered breathing in adults, Am J Epidemiol 177(9), 2013
[2] Frost & Sullivan, Hidden Health Crisis Costing America Billions

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About ResApp Health Limited

ResApp Health Limited (ASX: RAP) is a leading digital health company developing smartphone applications for the diagnosis and management of 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.