# SleepCheck Pre-Submission Package Lodged with the US FDA

- **Pre-Submission package lodged with FDA and meeting scheduled for November to progress clearance of SleepCheck for use in the US**
- **SleepCheck is ResApp's direct-to-consumer sleep apnoea screening application**
- **FDA Pre-Submission lodgement follows regulatory approvals in Europe and Australia**
- **The US is a large market opportunity with 22m sleep apnoea sufferers and a negative economic impact of ~US$150Bn due to accidents and lost productivity[i]**

**Brisbane, Australia, 21 September 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 advise that it has filed a Pre-Submission package with the United States (US) Food and Drug Administration (FDA) and requested a meeting with the regulatory body to progress 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 the user's smartphone to make an assessment.

SleepCheck was launched in June following a large clinical study and has achieved regulatory approval in Australia and Europe. SleepCheck is available on the App Store for iPhone in Europe (including the United Kingdom), Australia, New Zealand, Hong Kong and Singapore.

The Pre-Submission package was lodged as part of the FDA's Pre-Submission Program which provides applicants with the opportunity to obtain targeted feedback from the organisation in response to questions related to their marketing application or data requirements prior to a pre-market submission.

ResApp has scheduled a Pre-Submission meeting with the FDA to discuss the 510(k)[ii] regulatory pathway for SleepCheck. During this meeting, the company will work cooperatively with the regulatory body and discuss any additional human factors testing or clinical data requirements which may be necessary to progress FDA clearance. The meeting is scheduled to take place in November.

**CEO and Managing Director Dr Tony Keating said:** *"The Pre-Submission meeting with the FDA provides us with important feedback on the requirements to launch SleepCheck in the USA. We have been through the regulatory approval process with SleepCheck in a number of countries and we have a track record of success in this regard. We are confident we will achieve the same outcome in the US.*

**ResApp Health Limited** ABN 51 094 468 318
Level 12, 100 Creek St, Brisbane QLD 4000 Australia
**T** +61 7 3724 0035 **E** info@resapphealth.com.au **W** www.resapphealth.com.au

*"The US is a big opportunity for us. There are an estimated 22 million Americans suffering from sleep apnoea and approximately 80% of cases of moderate or severe obstructive sleep apnoea are undiagnosed, creating an economic burden of nearly US$150Bn. SleepCheck would provide a low cost, accessible screening tool and potentially reduce the health and economic impact of the condition.*

*"We look forward to providing regular updates to shareholders on the outcome of the meeting and the application's broader market progress in the coming months."*

###

**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.

**Contacts**

Dr Tony Keating
CEO and Managing Director
+61 430 180 659
tony@resapphealth.com.au

Mr Brian Leedman
Vice President, Corporate Affairs
+61 412 281 780
brian@resapphealth.com.au

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

---

[i] American Academy of Sleep Medicine and Frost & Sullivan report: "Hidden health crisis costing American billions"
[ii] https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/510k-clearances