ResApp Receives Positive Results from Prospective At-Home Sleep Apnoea Study

Brisbane, Australia, 30 September 2019 – ResApp Health Limited (ASX:RAP), a leading digital health company developing smartphone applications for the diagnosis and management of respiratory disease, is today pleased to announce positive top-line results from its prospective, blinded at-home obstructive sleep apnoea study. ResApp's algorithms, which analyse a person's breathing and snoring sounds recorded using a smartphone placed on a bedside table, were able to accurately identify obstructive sleep apnoea (OSA) when compared to a simultaneous at-home comprehensive sleep study.

A total of 308 patients were recruited for the study. Patients with incomplete clinical data (13) and those who had a partner or pet in the room (57) were excluded. 238 patients were analysable, of which 37% were female. The mean age of patients was 49 years (range 18-82) with a mean apnoea hypopnoea index (AHI) of 27/h (range 0-119/h). The study principal investigators were Dr Philip Currie and Dr Ivan Ling of Cardio Respiratory Sleep (CRS).

The study endpoints were the algorithms' performance in identifying three severities of OSA, mild (AHI ≥ 5/h), moderate (AHI ≥ 15/h) and severe (AHI ≥ 30/h) when compared to an American Academy of Sleep Medicine (AASM) Type II sleep study (full, but unattended polysomnography) performed simultaneously in the patient's home.

For all three AHI thresholds, the area under the receiver operating characteristic curve (AUC), a measure of performance which takes into account both sensitivity and specificity, was greater than 0.91 demonstrating that ResApp's algorithms, when used at-home, have an excellent ability to identify mild, moderate or severe OSA.

ResApp's algorithms correctly identified patients with OSA across the three AHI thresholds, with a sensitivity of 85%, 83% and 83% for AHI thresholds of 5/h, 15/h and 30/h respectively. At these thresholds the algorithms had a specificity of 73%, 80% and 90%. The measure of specificity for AHI threshold of 5/h was limited due to the low numbers of study participants with very low AHI.

"We achieved excellent performance previously during our in-laboratory sleep studies and it is great to see the same high levels of performance replicated in our intended use setting, in peoples' homes," said Tony Keating, CEO and Managing Director of ResApp. "Nearly one billion people suffer from sleep apnoea and 80% of those with moderate or severe sleep apnoea remain undiagnosed. By delivering a highly scalable, low cost smartphone app for OSA screening we have a huge opportunity to reduce the health and economic impact of undiagnosed OSA. We will now move forward into the regulatory submission and commercialisation phases of this exciting project."

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Dr Philip Currie, study principal investigator, said, "This very large study, which recruited over 2,000 patients, conducted both in the sleep laboratory and at home has developed and validated a simple and accurate screening tool using only a smartphone in the bedroom. The clinical need is great and growing and it remains unaddressed by today's methods such as questionnaires and Type IV sleep testing devices."

A summary of the performance, including area under the receiver operating characteristic curve (AUC), sensitivity and specificity, for three AHI thresholds is presented in the table below.

	Patients[1]		**AUC**	**Sensitivity**	**Specificity**
	Y	**N**	**(95% CI)**	**(95% CI)**	**(95% CI)**
AHI ≥ 5/h (Mild)	212	26	0.91 (0.85-0.96)	85% (80-90%)	73% (52-88%)
AHI ≥ 15/h (Moderate)	136	92	0.91 (0.87-0.95)	83% (76-89%)	80% (71-88%)
AHI ≥ 30/h (Severe)	75	153	0.93 (0.90-0.96)	83% (72-90%)	90% (84-94%)

1. Number of patients clinically scored above or below the AHI threshold where the algorithms provided a result. For each test, the algorithms were not able to provide a result for a small number of patients [AHI ≥ 5/h, 0 (0%) patients; AHI ≥ 15/h, 10 (4%) patients; AHI ≥ 30/h, 10 (4%) patients].

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About Sleep Apnoea

Sleep apnoea is a common sleep disorder where the person repeatedly stops breathing or has periods of shallow breathing during sleep. Data from the Wisconsin Sleep Cohort Study showed that sleep apnoea affects more than three in ten men and nearly two in ten women. 80 percent of people suffering moderate and severe sleep apnoea are undiagnosed. Untreated, obstructive sleep apnoea is known to increase the risk of heart disease, hypertension, stroke and type 2 diabetes, and is estimated by the American Academy of Sleep Medicine to cost the US economy $149.6 billion annually.

About Apnoea Hypopnoea Index (AHI)

The Apnoea Hypopnoea Index (AHI) is the number of apnoeas (complete blockages of the airways) or hypopnoeas (partial blockages of the airways) recorded during the study per hour of sleep. It is generally expressed as the number of events per hour. Based on AHI, the severity of obstructive sleep apnoea is classified as: none/minimal (AHI less than 5 per hour), mild (AHI greater than or equal to 5 but less than 15 per hour), moderate (AHI greater than or equal to 15 but less than 30 per hour) or severe (AHI greater than or equal to 30 per hour).

About Area under the ROC Curve (AUC), Sensitivity and Specificity Measures

The area under the receiver operating characteristic (ROC) curve (AUC) is a measure of how well a test can distinguish between two diagnostic groups. AUC takes values from 0 to 1, where a value

of 1 reflects a perfectly accurate test. In general, an AUC of 0.5 suggests no discrimination, 0.7 to 0.8 is considered fair, 0.8 to 0.9 is considered good, and more than 0.9 is considered excellent. Sensitivity is the proportion of patients with the disease who test positive. Specificity is the proportion of patients without the disease who receive a negative test result.

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 hardware. Clinical studies have demonstrated accurate diagnosis of lower respiratory tract disease, upper respiratory tract infection, pneumonia, bronchiolitis, croup, asthma exacerbation/reactive airway disease, chronic obstructive pulmonary disease, chronic obstructive pulmonary disease exacerbation, and obstructive sleep apnoea. ResApp's smartphone-based acute respiratory disease diagnostic test, ResAppDx-EU, is CE Marked in the European Union. Potential customers of ResApp's products include healthcare providers in telehealth, emergency department, urgent care and primary care settings as well as humanitarian organisations in the developing world.

For more information, please visit www.resapphealth.com.au.

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