

**ASX / MEDIA RELEASE**

## **ResApp Announces Positive Top-line Results from Australian Prospective Paediatric Clinical Study**

**ResApp to hold conference call today at 11am Australian Eastern Standard Time**

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Conference ID: 659 7984

**Brisbane, Australia, 3 September 2018** -- ResApp Health Limited (ASX:RAP), a leading digital health company developing smartphone applications for the diagnosis and management of respiratory disease, today announced excellent top-line results from its Breathe Easy paediatric double-blind, prospective clinical study using machine learning algorithms to diagnose respiratory disease from cough sounds recorded on a smartphone. The algorithms were invented by Associate Professor Udantha Abeyratne and his team at The University of Queensland (UQ) and further co-developed by ResApp and UQ. Independent statistical analyses of the Breathe Easy study, performed by Curtin University health researchers, confirmed ResApp's algorithms accurately diagnose a broad range of childhood respiratory diseases when compared to clinical diagnoses.

Data from 585 patients was analysed. The age of study participants ranged from 29 days to 12 years, 41% were female and 28% were less than two years old.

For all predefined study endpoints, ResApp's algorithms performed very well, achieving a positive percent agreement (PPA) between 79% and 97% and a negative percent agreement (NPA) between 80% and 91% when compared to a clinical diagnosis. The results for asthma/reactive airway disease (RAD) were exceptional, with a PPA of 97% and an NPA of 91%. Asthma/RAD diagnosis is typically performed in the clinic using an inhaled bronchodilator test, which is time consuming and costly. For pneumonia, a disease that is responsible for the death of more children under five than any other disease, ResApp's algorithms delivered a PPA of 87% and an NPA of 85%. For lower respiratory tract disease, a key diagnosis for telehealth consultations in particular, ResApp's algorithms yielded a PPA of 83% and an NPA of 82%. While a shortage of patients under two without bronchiolitis limited the statistical robustness of the study's bronchiolitis results, the algorithm's performance was again excellent with PPA and NPA both above 80%.

According to Dr Paul Porter, MBBS, FRACP, the study principal investigator at Joondalup Health Campus and Princess Margaret Hospital, "Even with all the information available to us in a modern, well-equipped hospital we still face difficulties in diagnosing childhood respiratory diseases. These excellent prospective results, obtained without the need to examine the patient

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or perform investigations, will give clinicians significantly more confidence in their diagnosis of respiratory disease, especially in telehealth and emergency department settings. I am grateful to all the patients who participated in the study, as well as the clinical research teams at Joondalup Health Campus and Princess Margaret Hospital who showed great expertise and dedication in performing the study.”

A summary of the number of patients with each disease, PPA and NPA for the study endpoints is presented in the table below.

	Patients <sup>3</sup>		Positive Percent Agreement	Negative Percent Agreement
	Y	N		
Lower respiratory tract disease <sup>1</sup>	419	154	83% (95% CI, 79-86%)	82% (95% CI, 75-88%)
Asthma/reactive airway disease <sup>1</sup>	149	381	97% (95% CI, 92-99%)	91% (95% CI, 88-94%)
Croup <sup>2</sup>	68	500	88% (95% CI, 78-95%)	86% (95% CI, 82-89%)
Pneumonia <sup>1</sup>	60	509	87% (95% CI, 75-94%)	85% (95% CI, 82-88%)
Primary upper respiratory tract disease <sup>1</sup>	89	482	79% (95% CI, 69-87%)	80% (95% CI, 76-83%)
Bronchiolitis <sup>1</sup> (patients aged < 2 years old)	131	26	84% (95% CI, 77-90%)	81% (95% CI, 61-93%)

1. ResApp algorithm includes cough audio and patient reported symptoms as input.
2. ResApp algorithm includes cough audio as input only.
3. Number of patients clinically diagnosed as having disease (Y) or not having disease (N).

“The outstanding results delivered by the Breathe Easy prospective study are consistent with our expectations, and for diseases such as pneumonia and asthma have even exceeded our expectations. This formal confirmation of ResApp’s algorithms’ robust performance will allow us to provide key diagnostic products in an array of clinical settings, especially in telehealth - one of the fastest growing segments in healthcare - where up to 50% of consultations are respiratory related”, said Tony Keating, CEO and Managing Director of ResApp. “We now have a solid dataset to underpin our forthcoming CE mark and TGA submissions which will propel the commercialisation of our products in Europe, Australia and the rest of the world outside the US. The successful completion of Breathe Easy also gives us additional data, experience and confidence as we finalise our US SMARTCOUGH-C-2 study.”

ResApp also advises that clinical adjudication and final quality assurance is ongoing in its US SMARTCOUGH-C-2 study with top-line results now expected later this month.



### **About the Breathe Easy Paediatric Study**

The Breathe Easy paediatric study evaluated the efficacy of ResApp's cough-based diagnosis algorithms in diagnosing acute respiratory disease. The double-blind, prospective study recruited infants and children who presented to one of the two participating Australian hospitals with signs and symptoms of respiratory disease. The study endpoints were the positive percent agreement and negative percent agreement of ResApp's algorithms compared with a clinical diagnosis for lower respiratory tract disease, asthma/reactive airway disease, croup, bronchiolitis, pneumonia and primary upper respiratory tract disease. The clinical diagnosis was made by a clinical adjudication committee using all available clinical data, including radiology and microbiology.

### **About Positive and Negative Percent Agreement**

Published guidance by the US Food and Drug Administration recommends the terms positive and negative percent agreement be used instead of sensitivity and specificity when a new test is compared to a non-reference standard such as a clinical diagnosis. Positive percent agreement (the substitute for sensitivity) is the proportion of patients with the disease that test positive. Negative percent agreement (specificity) is the proportion of patients without the disease that test negative.

### **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 are underway at leading hospitals in the United States and Australia, and previous studies have demonstrated accurate diagnosis of pneumonia, asthma/reactive airway disease, bronchiolitis, croup, chronic obstructive pulmonary disease and upper respiratory tract infections. ResApp has also obtained excellent results for screening of obstructive sleep apnoea in a proof-of-concept clinical study. 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 on ResApp, visit [www.resapphealth.com.au](http://www.resapphealth.com.au)

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