

Positive preliminary results from current clinical study for diagnosing respiratory disease

- Greater than 95% accuracy achieved for distinguishing patients with asthma from healthy subjects
- Greater than 96% accuracy achieved for distinguishing patients with viral pneumonia from healthy subjects
- Successfully demonstrated that voluntary coughs can achieve high levels of accuracy – in addition to the spontaneous coughs used in previous studies

Perth, Western Australia, 30 September 2015 -- ResApp Health Limited (ASX:RAP), the developer of smartphone medical applications for the diagnosis and management of respiratory disease, today announced positive preliminary results from its paediatric clinical study currently underway at Joondalup Health Campus (JHC) in Perth, Western Australia. The preliminary results, prepared by the team led by Associate Professor Udantha Abeyratne at The University of Queensland (UQ), were calculated based on an initial 211 patient dataset.

In the preliminary analysis, three groups were identified within the dataset due to their clinical relevance and the fact that they were present in relatively large numbers:

Normal Group (39 subjects)	Healthy volunteers with no discernible respiratory illness at the time of measurement
Asthma Group (52 subjects)	Patients with a diagnostic classification of asthma or viral induced wheeze, with or without Upper Respiratory Tract Infection (URTI) as comorbidity
Viral Pneumonia Group (25 subjects)	Patients with a diagnostic classification of viral pneumonia alone or with comorbidities of URTI and/or viral induced wheeze. We consider only X-ray confirmed viral pneumonias

In addition to these groups, the dataset includes 95 patients diagnosed with URTI, croup, bronchiolitis, bacterial pneumonia or other respiratory diseases that were not considered in this preliminary analysis.

The performance of the algorithm was evaluated using the method of leave-one-out validation against the clinical diagnosis provided by the JHC clinical team. Performance was calculated using voluntary coughs alone as well as using a combination of voluntary and spontaneous coughs.

Key findings:

- **Asthma diagnosis:**
 - o Greater than 97% sensitivity, 92% specificity and greater than 95% accuracy (see below for definitions of sensitivity, specificity and accuracy)

for separating the Asthma Group from the Normal Group using cough sounds.

- **Viral pneumonia diagnosis:**
 - o Greater than 91% sensitivity, greater than 95% specificity and greater than 96% accuracy for separating the Viral Pneumonia Group from the Normal Group using cough sounds.
- Very little difference in performance in any cases was observed between using spontaneous (involuntary) and voluntary coughs in the disease groups studied.

Associate Professor Udantha Abeyratne commented, “The new results are exciting and provide an excellent beginning to our studies in the developed world. They further reinforce our hypothesis that cough sounds carry characteristic signatures of respiratory illnesses such as asthma and pneumonia. I am looking forward to refining our algorithms and covering additional diseases in the database in the future.”

“Today’s preliminary data is a significant step in our development of a respiratory disease diagnostic tool that provides instant answers and seamlessly integrates into telehealth platforms. It further gives us great confidence that the research team has developed robust and accurate algorithms,” said Dr Tony Keating, CEO and Managing Director of ResApp Health. “Such high levels of accuracy will support our regulatory strategy as we work towards FDA approval in late 2016 and will assist in our discussions with telehealth providers, international aid agencies and others regarding partnership opportunities.”

These results are a significant advance over the results obtained by UQ from their Bill and Melinda Gates Foundation-sponsored proof of concept clinical study performed in Indonesia. In particular,

1. An increase in subjects from 91 in Indonesia to 211 in the present study.
2. A focus on viral pneumonia in the present study. Note that bacterial pneumonia is typically treated using antibiotics, while antibiotics are typically not used for viral pneumonia cases.
3. The present study successfully validated the use of voluntary coughs as only spontaneous coughs were used in the Indonesian study.
4. The present study successfully validated performance using healthy subjects as the control group; such subjects were not available in the Indonesian study.

The present study (currently underway at both JHC and Princess Margaret Hospital) also includes high numbers of patients clinically diagnosed with URTI, croup and bronchiolitis. It also includes a growing number of patients with bacterial pneumonia. The team at UQ is currently adapting and training the algorithms on these additional diseases as well as further refining the algorithms for pneumonia and asthma. The team is also investigating the use of easily available patient data such age, gender, presence/absence of fever and breathing rate in further improving the diagnostic performance of the algorithms.

The Company notes that these results are preliminary and may change as the clinical study progresses and more patients are added to the dataset.

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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

About Sensitivity, Specificity and Accuracy Measures

Sensitivity is the proportion of patients with the disease that test positive. Specificity is the proportion of patients without the disease that will have a negative test result. Accuracy is a measure of both categories.

About ResApp Health Limited

Founded in 2014, ResApp Health Limited, through an exclusive license granted by the University of Queensland (UQ) is developing smartphone medical applications for the diagnosis and management of respiratory disease. The technology is based on a machine learning algorithm that uses sound alone without the need for additional hardware to diagnose and measure the severity of a respiratory condition. The algorithms have been successfully tested for pneumonia and asthma diagnosis in a clinical proof of concept study by UQ through funding from the Bill and Melinda Gates Foundation. Addressable markets for this technology include licensing to large telehealth service providers for 'in consultation' point of care diagnosis, at-home diagnosis and management of respiratory disease through direct sales to consumers and healthcare providers, and working with global aid and humanitarian organisations to deliver tools for low-cost diagnosis in the developing world.

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