



CEO's Prepared Statement for Investor Conference Call on the SMARTCOUGH-C-2 Study Preliminary Results

Brisbane, Australia, 31 October 2018 -- ResApp Health Limited (ASX:RAP), a leading digital health company developing smartphone applications for the diagnosis and management of respiratory disease, is pleased to provide a copy of ResApp's Chief Executive Officer's prepared statement for the Investor Conference Call to be held at 11am AEDT on Wednesday 31 October 2018 to discuss the preliminary results from its SMARTCOUGH-C-2 study.

Good morning everybody and thank you for joining our call. Today I would like to discuss the preliminary results from our SMARTCOUGH-C-2 study that we released to the market yesterday. We are very pleased with these positive results as they allow us to submit to the US FDA for approval for at least three indications, lower respiratory tract disease, upper respiratory tract disease and asthma/reactive airway disease. We will very likely add croup to this list for approval as well, considering our previous results for croup. These actions, in conjunction with our forthcoming submission for European CE and Australian TGA approval for six indications, lower respiratory tract disease, upper respiratory tract disease, asthma/reactive airway disease, croup, bronchiolitis and pneumonia, based on our very strong Australian study results, move us into the next exciting phase for the company as we make real tangible progress towards commercialisation worldwide. This is an exciting time for ResApp.

SMARTCOUGH-C-2 is a multi-site, prospective, double-blind study evaluating the efficacy of the ResAppDx in the diagnosis of childhood acute respiratory disease using cough sounds. We enrolled 1,470 children who presented to one of the three participating sites in the United States with signs or symptoms of acute respiratory disease. The study's co-primary endpoints were positive and negative percent agreement with clinical diagnosis for pneumonia, lower respiratory tract disease, bronchiolitis, asthma/reactive airway disease, upper respiratory tract disease and croup. All of these primary endpoints are treated equally and independently from a clinical study perspective, but upper respiratory tract disease and lower respiratory tract disease by far represent the greatest commercial opportunity for ResApp, as I will now explain.

Firstly, I would like to describe the clinical adjudication process taken in the SMARTCOUGH-C-2 study. Clinical diagnosis of respiratory disease is not clear cut. It is a step-by-step process combining clinical judgement with a number of diagnostic aids such as auscultation with a stethoscope, chest x-ray, blood and sputum tests. There is little published information on the accuracy of clinicians' diagnosis of respiratory disease as there is no gold standard to compare to. In the SMARTCOUGH-C-2, and Breathe Easy studies, we used multiple adjudicators to try to get the most accurate clinical diagnosis possible as a comparator to ResAppDx performance. Firstly, two adjudicators review a patient's complete medical record and independently make a diagnosis. If they do not agree, then a third independent adjudicator is used.

ResApp Health Limited ABN 51 094 468 318

Headquarters: Level 8, 127 Creek St, Brisbane QLD 4000 Australia

Registered Office: Level 24, 44 St Georges Tce, Perth WA 6000 Australia

T +61 8 6211 5099 E info@resapphealth.com.au W www.resapphealth.com.au

Importantly, the adjudication process also gives us insight into the accuracy of clinicians and we found that in one-third of cases (over 400 patients), the first two adjudicators did not agree on the diagnosis and a third was required to form a consensus, i.e. only in 66% of cases did the first two adjudicators agree with each other. This gives us a very large dataset of clinician accuracy, which will also form part of our FDA submission, allowing us to directly show how ResAppDx performance compares to clinician performance. It highlights the disparity between individual diagnoses made by respiratory specialists with the information available to them from existing tools.

I've been asked more than a few times since yesterday if I am concerned that our results are in the seventies rather than the eighties and my answer is a resounding - no. If you consider the agreement figures that I've just described, then our algorithms agreed with the final consensus more often than either of the first two adjudicators, which is excellent.

Based on the results from the study we plan to immediately prepare an FDA *de novo* submission for three indications, lower respiratory tract disease, upper respiratory tract disease and asthma/reactive airway disease, with potentially croup to be included once we receive those results. These three indications show robust results and they represent very large commercial opportunities for us in the US.

In practice, clinicians follow a logical process to narrow down their diagnosis step-by-step to a specific disease. ResApp has the algorithms to support this well-established procedure and will benefit greatly in doing so.

Clinically, the differentiation between upper and lower respiratory tract disease is an extremely important first step in the differential diagnosis of a patient and must be undertaken with all patients who present with symptoms of a respiratory disease. Upper respiratory tract diseases tend to be milder and include the common cold, sinusitis and pharyngitis. Lower respiratory tract diseases tend to be more serious and include asthma and pneumonia. One of the main aids clinicians use to perform this differentiation is the stethoscope. However, it is well known that this is very subjective. Our algorithms are objective and their results are repeatable. They can be used in hospitals, clinics, GP offices, and especially in telehealth (where no stethoscope is available). Our results for identifying lower respiratory disease are strong and robust, with a positive percent agreement of 73% and a negative percent agreement of 77%. Our ability to differentiate between upper and lower respiratory tract disease addresses the entire population of children with respiratory disease and is the key decision point in the clinical diagnostic pathway. In practice, ResApp's upper and lower respiratory tract disease algorithms would be applied to support or complete this step, before a more detailed diagnosis was pursued.

When considering market size, asthma is the most prevalent lower respiratory tract disease, affecting 8.3% of all children. It is the second most common reason for somebody under the age of 45 to visit their primary care physician in the US and is one of the most common reasons for hospital admissions of children in the US. Asthma/reactive airway disease diagnosis is typically performed in the clinic using an inhaled bronchodilator test. This testing is clearly not available



during a telehealth consultation, and even in urgent care and emergency departments this is subjective, time consuming and costly. We have always received very strong results for asthma and in the SMARTCOUGH-C-2 study we reached 75% positive percent agreement and 84% negative percent agreement.

It is clear that in the US pneumonia diagnosis is materially different to what we saw in our Australian study. We see a significantly higher incidence of chest x-ray usage and higher dependence on those chest x-rays, despite their fallibility. Also, if the adjudicators, who are the reference, only agree 66% of the time then clearly, pneumonia diagnosis in the US is not as rigid and repeatable as it may be elsewhere. In such circumstances, it's statistically difficult for ResAppDx to achieve performance figures that are much different than the figures achieved by the adjudicators themselves.

ResApp was founded on a single algorithm designed to diagnose pneumonia in children in the developing world. It is the developing world where pneumonia has a high prevalence, while in the US it is a low prevalence disease. Pneumonia patients were a small single digit percentage in our study, compared to over 50% of patients having upper respiratory tract disease, 30% of patients having lower respiratory tract disease and 15% of patients having asthma. As the company has grown and interacted more with the clinical diagnostic community we have developed diagnostic tools for multiple diseases, but arguably, the most important and the most commercially significant tool is our ability to differentiate between upper and lower respiratory tract disease. Addressing this critical first step in the diagnostic process opens up an enormous market for ResApp because it applies to 100% of the patients that present with respiratory symptoms. Our additional algorithms, which focus on the next level of diagnosis (asthma, croup, etc), provide additional clarity to clinicians and additional commercial opportunities for ResApp.

The results from our studies prove that ResAppDx is a valuable tool for clinicians worldwide and will have myriad commercial applications, especially in telehealth. The substantial degree of disparity between clinicians' diagnosis further highlights the need and value of an objective diagnostic tool. From a financial perspective, our submissions for TGA, CE and FDA approval will unlock access to the largest elements of the respiratory disease diagnostic market worldwide. And it's all happening within the next few months.

About ResApp Health Limited

ResApp Health Limited (ASX: RAP) is a 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 at leading hospitals in the United States and Australia 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 prospective clinical study. Potential customers of ResApp's

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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

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

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