ResApp Files Pre-Submission Package with the US FDA

Perth, Western Australia, 31 December 2015 -- ResApp Health Limited (ASX: RAP), the developer of smartphone medical applications for the diagnosis and management of respiratory disease, today announced that it has filed a Pre-Submission package with the United States Food and Drug Administration (FDA) for ResApp's diagnostic mobile software application (app).

ResApp has requested a meeting with the FDA to work cooperatively on the regulatory and clinical plan to support FDA approval of ResApp's smartphone app. The meeting is expected to take place in the first quarter of 2016. The FDA's Pre-Submission Program is designed to provide applicants the opportunity to obtain targeted feedback from the FDA in response to questions related to their marketing application, clinical study protocols or data requirements prior to a premarket submission.

ResApp plans to pursue US commercialisation as a Class II device supported with clinical data. The specific requirements for a future FDA submission will be discussed at the Pre-Submission meeting with the FDA. ResApp is on track to file a premarket submission with the FDA in mid 2016.

The Pre-Submission package was prepared with the assistance of Experien Group, LLC, a firm of highly experienced Silicon Valley-based FDA consultants who have an excellent track record of FDA regulatory submission approvals and clearances.

Michael Billig, CEO of Experien Group said, "Experien Group and ResApp have submitted a comprehensive Pre-Submission package to the FDA that includes a detailed description of their smartphone medical app, an in-depth risk-benefit analysis, a summary of the clinical results to date and a proposed clinical study plan. The feedback obtained from the FDA will provide ResApp and Experien Group with an insight into the FDA's requirements for the data required to support a FDA submission."

Dr Tony Keating, CEO and Managing Director of ResApp said, "Filing this Pre-Submission package marks a major step towards FDA approval. The resulting meeting with the FDA will solidify our clinical and regulatory plan, clarifying US requirements for approval as we move as quickly as possible to make our technology available in the US telehealth market."

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About ResApp Health Limited

ResApp Health Limited, founded in 2014, is developing smartphone medical applications for the diagnosis and management of respiratory disease. The technology is based on machine learning algorithms that use sound alone to diagnose and measure the severity of respiratory conditions without the need for additional hardware. The algorithms were initially developed by The University of Queensland with funding from the Bill and Melinda Gates Foundation. ResApp has a multi-site clinical study underway and preliminary results demonstrated accurate diagnosis of pneumonia, asthma/viral wheeze, bronchiolitis, croup and upper respiratory tract infections in children. Approval has been recently received to extend the study to adults. Markets for ResApp's technology include telehealth use through partnerships with telehealth service providers, emergency department and regular clinic use by healthcare providers, at-home use by consumers and working with global aid and humanitarian organisations to deliver tools for the developing world.

For more information on ResApp, visit www.resapphealth.com.au