FDA Consultant Engagement

- **Experien Group, LLC, a leading Silicon Valley-based FDA regulatory consultant engaged**
- **ResApp and Experien to target a Pre-Submission Meeting with the FDA by the end of the year**
- **Key software developer hires made**
- **Research agreement with The University of Queensland signed**

Perth, Western Australia, 3 September 2015 - ResApp Health Limited (ASX: RAP), the developer of smartphone medical applications for the diagnosis and management of respiratory disease, is pleased to announce that Experien Group, LLC of Sunnyvale, California has been engaged as regulatory consultants. Experien Group is a firm of highly experienced Silicon Valley-based FDA consultants who have achieved a 99% approval rate for regulatory submissions. The senior staff have been responsible for over 1,000 successful FDA and international regulatory submissions over their careers. They have extensive experience in Premarket Approvals, 510(k) and de novo applications, including submissions for mobile medical apps. In 2015, Experien received FDA 510(k) clearance for a software product that performs personalized physiological analytics using machine learning algorithms.

ResApp will work with Experien Group to prepare and submit a Pre-Submission package to the FDA, with the aim of conducting a Pre-Submission Meeting with the FDA by the end of this year. The purpose of this Pre-Submission Meeting will be to introduce ResApp and the technology to the FDA prior to any formal submissions.

Dr Tony Keating, CEO and Managing Director of ResApp Health said, “The appointment of Experien Group is central to the company’s regulatory approval strategy and we look forward to working with them. Experien Group’s experience, in particular in obtaining FDA 510(k) clearance for machine learning mobile medical apps, makes them an ideal partner as we move quickly to bring our innovative technology to market.”

The Pre-Submission Meeting with the FDA will be a significant milestone in ResApp’s plans to expedite commercialisation of its technology in the U.S., in particular for ResApp’s focus on providing a regulatory-approved diagnostic test to be used alongside, or prior to, a telehealth consultation.

The FDA's Pre-Submission Program is designed to give 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 (Premarket Approval, 510(k), de novo, etc).

Blue Curve Pty Ltd, an Australian-based consultant with extensive FDA software quality system requirements experience has also been engaged.

In other developments, the company has recently filled key positions by hiring two highly experienced software engineers who, combined, bring over 40 years experience in mobile app development and audio digital signal processing to the company.

Completing ResApp's commitment under the terms of the original licensing agreement, a research agreement has been executed with UniQuest, to fund three senior engineers at The University of Queensland to analyse data, prepare results from the clinical studies and to refine and validate algorithms for respiratory conditions in addition to asthma and pneumonia. The agreement is valid for one year.

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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 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.

www.resapphealth.com.au