



**ASX / MEDIA RELEASE**

## **ResApp Submits CE Mark Technical File for Acute Respiratory Disease Diagnostic Smartphone Application**

**Brisbane, Australia, 2 January 2019** -- ResApp Health Limited (ASX:RAP), a leading digital health company developing smartphone applications for the diagnosis and management of respiratory disease, is pleased to announce that it has submitted its CE Mark Technical File to its European Notified Body, the British Standards Institution (BSI), for a first-of-its-kind smartphone application for the diagnosis of acute paediatric respiratory disease. ResAppDx-EU is a mobile software application to be used by clinicians for the diagnosis of lower respiratory tract disease, croup, pneumonia, asthma/reactive airway disease and bronchiolitis in infants and children. CE Marking will enable the commercial sale of ResAppDx-EU in the European Economic Area and facilitate commercialisation in other markets such as Australia, Canada and Singapore.

“The preparation and filing of the CE Mark Technical File for ResAppDx-EU, our flagship acute respiratory disease diagnostic tool, is an exciting moment for ResApp as it unlocks the last element required to commercialise our first product,” said Tony Keating, CEO and Managing Director. “Europe represents a very attractive opportunity with a large portion of the continent’s six billion annual general practitioner visits related to respiratory disease. ResAppDx-EU will provide clinicians with the first rapid and accurate test for the most commonly-seen acute respiratory diseases. It has the potential to have far-reaching benefits for the healthcare system and we are working with a German private hospital network this European winter to quantify these benefits.”

ResApp plans to file a De Novo premarket submission for its acute paediatric respiratory disease diagnostic smartphone application with the US Food and Drug Administration in the first quarter of this calendar year.

ResApp has two other major clinical programs underway; an acute adult respiratory disease diagnosis study in which clinical adjudication is expected to finish this quarter and an at-home obstructive sleep apnoea study in which recruitment is nearly complete. As announced previously, a technical issue prevented clinical adjudication for croup in ResApp’s acute paediatric respiratory disease diagnosis study in the US, SMARTCOUGH-C-2, however this has been resolved and adjudication is expected to be completed this quarter.

### **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 at leading hospitals in Australia and the United States have demonstrated accurate diagnosis of lower respiratory tract disease, upper respiratory tract infections, asthma/reactive airway disease, pneumonia, bronchiolitis, croup,

**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](mailto:info@resapphealth.com.au) W [www.resapphealth.com.au](http://www.resapphealth.com.au)



chronic obstructive pulmonary disease and obstructive sleep apnoea. 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)

#### **Contacts**

Dr Tony Keating  
CEO and Managing Director  
+61 430 180 659  
[tony@resapphealth.com.au](mailto:tony@resapphealth.com.au)

Mr Brian Leedman  
Vice President, Corporate Affairs  
+61 412 281 780  
[brian@resapphealth.com.au](mailto:brian@resapphealth.com.au)

**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](mailto:info@resapphealth.com.au) **W** [www.resapphealth.com.au](http://www.resapphealth.com.au)