

ResApp to progress clinical study to develop COVID-19 smartphone-based screening test

- US-based clinical research study to explore relationship between cough sounds and COVID-19
- ResApp aims to develop a smartphone-based algorithm to identify people with suspected COVID-19 through their cough sounds using ResApp patented technology
- Algorithm may have applicability within health systems and broader settings where rapid, mass screening would be of significant value
- Leading US genomics company Phosphorus engaged to provide gold standard PCR testing as reference standard
- Phosphorus has developed a COVID-19 RT-qPCR at-home saliva test which has secured Emergency Use Authorisation from the US FDA
- Study protocol will be submitted to an Institutional Review Board for approval shortly with recruitment expected to commence this month

Brisbane, Australia, 11 March 2021 – ResApp Health Limited (ASX:RAP), a leading digital health company developing smartphone applications for the diagnosis and management of respiratory disease, is pleased to advise that it will shortly commence a US-based clinical study to explore the relationship between cough and SARS-CoV2 ("COVID-19") infection. ResApp has engaged Phosphorus, a leading US clinical-grade testing company to provide at-home COVID-19 testing for the study.

ResApp will conduct a pilot clinical study to secure data to train an algorithm to identify COVID-19 through cough sounds recorded on a smartphone, using a gold standard at-home salivabased Polymerase Chain Reaction (PCR) pathology test as a reference standard.

ResApp's regulatory approved cough-based machine-learning technology only requires a smartphone and is currently used to assist clinicians in the diagnosis of patients for a range of respiratory conditions. The company is confident that the ability to identify COVID-19 will considerably strengthen its offering and applicability both within health systems and potentially broader settings where rapid, mass screening would be of considerable value.

The company will actively recruit patients from COVID-19 hotspot areas in the US that are either symptomatic or asymptomatic who have a high likelihood of having COVID-19. First patient recruitment is expected to occur in the coming weeks following Institutional Review Board (IRB)



approval. The study aims to recruit up to 1,500 subjects with data collection expected to take up to two months.

To support the study, ResApp has signed a laboratory services agreement with leading New York based genomics and diagnostics company, Phosphorus (www.phosphorus.com) to provide at-home COVID testing for the study. Phosphorus has a suite of best-in-class genomic tests that have helped thousands of people avoid disease and live healthier lives.

Most recently, Phosphorus has been focused on the development and roll out of COVID-19 tests for individuals, employers and organisations. The group has developed an at-home saliva collection test for COVID-19, which has Emergency Use Authorisation from the US Food and Drug Administration.

During the study, ResApp will collect cough sample and symptom data from participants who will then be sent a Phosphorous at-home saliva collection kit. After providing their saliva sample, participants will ship the completed test kit to Phosphorous' CAP-accredited and CLIA-certified lab for PCR testing, allowing ResApp to detect and confirm whether or not a patient has COVID-19. A second cough sample will then be taken from patients to bolster the study dataset.

CEO and Managing Director Dr Tony Keating said: "While much progress has been made, the effects of COVID-19 are expected to continue well into the foreseeable future and we are confident that the development of this smartphone-based screening test will become an important and useful tool in many settings both within health systems and more broadly.

"Securing the agreement with Phosphorus to support the study is an important step in gathering the high-quality US data needed to develop robust and accurate algorithms, in particular when combined with our large existing dataset of patients with non-COVID-19 lower respiratory tract illnesses. Phosphorus has considerable experience in COVID-19 testing and its test will allow ResApp to obtain gold standard COVID-19 status from patients in the comfort of their own home. By recruiting in the at-home setting, we will have symptomatic and asymptomatic patients, an important factor in COVID-19 as it is both highly contagious and has considerably variability in its impact on patients.

"Once developed, we anticipate that the algorithm, easily deployed on a smartphone, to have wide application, in particular in the mass screening of individuals.

"Additionally, in combination with our ResAppDx product, we may be able to identify COVID-19 patients that are facing a more rapid disease progression, allowing them to seek further telehealth treatment or urgent care review. This will reduce the burden on healthcare facilities and assist patients in seeking the correct medical treatment.

"We look forward to updating shareholders on first patient recruitment and developments in the coming weeks."



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About ResApp Health Limited

ResApp Health Limited (ASX: RAP) is a leading digital health company developing smartphone applications for the diagnosis and management of the respiratory disease. ResApp's machine learning algorithms use sound to diagnose and measure the severity of respiratory conditions without the need for additional accessories or hardware. ResApp's regulatory-approved and clinically validated products include ResAppDx, a smartphone-based acute respiratory disease diagnostic test for use in telehealth, emergency department and primary care settings; and SleepCheck, a smartphone application which allows consumers to self-assess their risk of sleep apnoea. Both products are CE Marked in Europe and TGA approved in Australia. For more information, please visit <u>www.resapphealth.com.au</u>.

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This ASX announcement was approved and authorised for release by the board of directors of ResApp Health.