ResApp announces positive results for a new novel smartphone-based COVID-19 screening test

Company to host conference call today at 1:30PM AEDT

Details posted at end of release

- **92% sensitivity for detecting COVID-19 with a new cough audio-based algorithm – exceeding the real-world measured sensitivity of rapid antigen testing**
- **Initial market opportunities in settings where frequent testing is required – employee, healthcare worker and student screening, travel, sports, entertainment, and aged care**
- **ResApp to engage with regulators on requirements for approvals and seek to partner with a global health or technology company to accelerate commercialisation**

Brisbane, Australia, 22 March 2022 – ResApp Health Limited (ASX:RAP), a leading digital health company developing smartphone applications for the diagnosis and management of respiratory disease, today announced positive results for a new novel cough audio-based COVID-19 screening test that only requires a smartphone. In a pilot clinical trial of 741 patients (446 COVID-19 positive) recruited in the United States and India, ResApp's screening test, which uses machine learning to analyse the sound of a patient's cough, was found to correctly detect COVID-19 in 92% of people with the infection.

ResApp's algorithm achieved an area under the curve (AUC) of 0.93 using cough audio and patient-reported symptoms across both trials. AUC is a standard measure of how well a test distinguishes between two diagnostic groups, where a value of 1 represents a perfect test. A value greater than 0.9 is considered outstanding[i].

With this AUC, ResApp can select different operating points depending on the setting to achieve either high sensitivity, high specificity, or a balanced sensitivity and specificity. For use as a screening test prior to a rapid antigen or polymerase chain reaction (PCR) test to rule out COVID-19, an operating point that provides a 92% sensitivity and 80% specificity could be selected. This sensitivity exceeds the real-world measured sensitivity of rapid antigen tests[ii,iii]. The combination of high sensitivity and 80% specificity results in 8 out of 10 people without COVID-19 being correctly screened as negative and not requiring a follow-on rapid antigen or PCR test.

ResApp will initially target use in settings where frequent COVID-19 testing is required, such as employee, healthcare worker and student screening, travel, sports, entertainment, and aged care. In these settings a high sensitivity test that only requires a smartphone would significantly reduce the number of rapid antigen or PCR tests required, improving availability, reducing costs, and reducing environmental impact. A smartphone-based test also has the ability to improve security and reporting of results using biometric identification such as facial recognition.

ResApp Health Limited ABN 51 094 468 318
Level 12, 100 Creek St, Brisbane QLD 4000 Australia
T +61 7 3724 0035 **E** info@resapphealth.com.au **W** www.resapphealth.com.au

To ensure that the algorithm is specific to COVID-19 it was tested against the Breathe Easy dataset. The Breathe Easy dataset was collected prior to the COVID-19 pandemic and was used to train and validate ResApp's existing regulatory-approved (Australian TGA and CE Mark) ResAppDx product for acute respiratory disease diagnosis. This dataset includes 1,007 patients with a variety of non-COVID-19-related respiratory conditions including upper respiratory tract infections, asthma exacerbations, COPD exacerbations and other viral lung infections including pneumonia. The algorithm achieved greater than 90% specificity for these patients. This important result demonstrates that the algorithm is identifying COVID-19 and not general respiratory illness.

Consistent performance was found in analysis of a range of subgroups, including study arm and location, age, gender, and vaccination status. While genomic sequencing was not available, analysis of the data over two time periods, one where Delta was the dominant variant and another where Omicron was dominant, demonstrated consistent performance. As expected, and similarly to rapid antigen tests, the algorithm showed lower performance in asymptomatic patients, although only a small number (14) of asymptomatic patients were recruited in the trials.

The performance of the algorithm was obtained using K-fold cross-validation to provide an estimate of performance on unseen data. ResApp intends to submit the results for publication in a peer-reviewed journal in the coming weeks.

Professor Catherine Bennett, Chair of Epidemiology at Deakin University, and a member of ResApp's COVID-19 Scientific Advisory Board said: *"The sheer scale of this global pandemic and the likely evolution to an endemic disease means we need more scalable diagnostic tools that can balance our current over-reliance on rapid antigen and PCR tests. By rapidly ruling out COVID-19, ResApp's COVID-19 test would significantly reduce the number of rapid antigen and PCR tests required, while still maintaining the disease surveillance needed to manage the continued impact of COVID-19. The simplicity, ease of use and unlimited scalability of ResApp's test will be welcomed by public health officials around the world."*

Tony Keating, CEO and Managing Director of ResApp added: *"We are very excited about these preliminary results for detecting COVID-19 using cough audio recorded on a smartphone. These algorithms offer a unique opportunity to provide a rule out screening test for COVID-19 at scale across the world, reducing the distribution challenge, the cost and the environmental impact of rapid antigen and PCR testing. The WHO have recently warned that the pandemic is not over, that health systems globally continue to strain under the current caseload and that we should be prepared for the potential of more dangerous variants to emerge. We intend to accelerate commercialisation by immediately engaging with regulators globally and we have already commenced discussions with global health and technology companies with the goal of rapidly bringing this product to market. These results also build our confidence in the development of patient management and monitoring tools for COVID-19 and expanding our research into long COVID."*

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Conference call details:
ResApp will hold a conference call today at 1:30pm Australian Eastern Daylight Time (AEDT) to discuss the above results and welcomes participation from interested parties. Tony Keating, CEO and Managing Director of ResApp, Mike Connell, VP, Commercial of ResApp and Professor Catherine Bennett, a member of ResApp's COVID-19 Scientific Advisory Board will host the call.

To register for the webcast, please follow this link:

https://us02web.zoom.us/webinar/register/WN_87-FcpBtTaiHUW97JM3zhA

Registered participants will receive a confirmation email containing the Zoom access link. The call will be recorded and made available on ResApp's website after the call.

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About ResApp's COVID-19 Clinical Trials
ResApp's COVID-19 clinical trials in the United States and India recruited subjects at multiple sites and environments, including at home, at testing clinics and in hospital. Gold standard, polymerase chain reaction (PCR) testing was used as a reference standard. The trials were run in partnership with Phosphorus (United States), Covid Clinic (United States) and Triomics (India). Details on the studies are available on clinicaltrials.gov (NCT04864535) and Clinical Trials Registry – India (CTRI/2021/09/036581). Refer also to ASX announcements on 11 March 2021, 9 August 2021 and 15 November 2021.

About Area under the Curve (AUC), Sensitivity and Specificity Measures
The area under the receiver operating characteristic (ROC) curve (AUC) is a measure of how well a test can distinguish between two diagnostic groups. AUC takes values from 0 to 1, where a value of 1 reflects a perfectly accurate test. In general, an AUC of 0.5 suggests no discrimination, 0.7 to 0.8 is considered acceptable, 0.8 to 0.9 is considered excellent, and more than 0.9 is considered outstanding[i]. Sensitivity is the proportion of patients with the disease who test positive. Specificity is the proportion of patients without the disease who receive a negative test result.

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 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 www.resapphealth.com.au.

Contacts

Dr Tony Keating
CEO and Managing Director
+61 430 180 659
tony@resapphealth.com.au

Mr Brian Leedman
Executive Director, Corporate Affairs
+61 412 281 780
brian@resapphealth.com.au

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

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[i] Hosmer Jr D.W., Lemeshow S. and Sturdivant R.X. (2013). *Applied Logistic Regression, Third Edition*. John Wiley & Sons.
[ii] Dinnes J., et al. (2021). Rapid, point-of-care antigen and molecular-based tests for diagnosis of SARS-CoV-2 infection. *Cochrane Database of Systematic Reviews*. https://doi.org/10.1002/14651858.CD013705.pub2
[iii] Hayer J., Kasapic D. and Zemmrich, C. (2021). Real-world clinical performance of commercial SARS-CoV-2 rapid antigen tests in suspected COVID-19: A systematic meta-analysis of available data as of November 20, 2020. *International Journal of Infectious Diseases, 108,* 592-602. https://doi.org/10.1016/j.ijid.2021.05.029