

30 November 2021

Dear fellow shareholders,

In my first shareholder letter in 2016, I talked about the trust that shareholders had placed in a new management team and a new technology that, while only recently spun-out of a university research lab, had the potential to improve healthcare on a global scale. We are now in the exciting position of starting to see this potential realised.

Over the past few years, we have strengthened our management team, bringing in leaders with great healthcare and technology sector experience. By conducting multiple clinical trials we have proven the technology, with clinical results now published in leading peer-reviewed journals. This has resulted in regulatory approvals in Australia, Asia, Africa and Europe, and our team has pushed our technology further forward, improving clinical accuracy, increasing real-world robustness, and expanding our capability to additional disease indications.

In late 2019 the world saw the emergence of a novel coronavirus. Later named SARS-CoV-2 (COVID-19) this virus has been called by many as one of the most damaging viruses ever documented. Its spread has adversely impacted the global economy and the global healthcare system. We have seen COVID-19 stretch healthcare systems to the brink.

To cope with increased demand, healthcare systems have needed to revolutionise their processes, as such technology has stepped in, and digital health adoption has accelerated over the past 24 months. According to McKinsey & Company, telehealth use in the US increased 38 fold from the pre-COVID-19 baseline. Investment in digital health has accelerated. According to Rock Health, \$14.7 billion was invested in US digital health deals in the first half of 2021, more than invested in all of 2020. This seismic shift in healthcare continues to provide significant tailwinds for ResApp.

We are the global leader in the use of audio as a biomarker for lung health and we continue to invest to maintain this leadership. This leadership has seen us secure landmark deals this year with leading global companies such as Janssen, AstraZeneca, Alodokter and Medgate. The products we have created, and the products in our pipeline, have the potential to improve the lives of billions of people globally.

## Key Partnerships in Acute Respiratory Disease

Our focus in 2021 has been securing the partnerships needed to bring ResAppDx, our lead acute respiratory diagnostic product, to as many clinicians and patients as possible. Adoption through these partners will build long term trust and confidence in our technology, driving further and wider adoption.

Remote care through telehealth represents a key opportunity for ResAppDx. We provide telehealth clinicians with the only regulatory approved way of accurately assessing and diagnosing patients who present with respiratory symptoms without the need of an additional,

specialised hardware device. Since our founding, this has been a key competitive advantage, giving telehealth clinicians the confidence that they can deliver the same level of care in a telehealth session that they would during an in-person visit.

While we have existing partners here in Australia, we are targeting important global markets for ResAppDx and earlier this year were pleased to announce that we had signed our first European telehealth deal with Medgate, a leading and well-respected Swiss telehealth company. During the year we have seen increased use of ResAppDx on Medgate's platform and importantly are seeing high patient satisfaction and increasing clinician confidence. We also continue to see clinical outcomes consistent with our published clinical trial data. We continue to work closely with Medgate as a foundational partner in Europe.

On the same day as we announced our Medgate agreement we announced that Alodokter, the largest provider of telehealth services in Indonesia, had also agreed to launch ResAppDx on their telehealth service. Our deal with Alodokter has the potential to see exponential growth in the use of ResAppDx as Alodokter connects over 50,000 doctors with millions of Indonesian patients.

These two deals represent a considerable amount of work by the ResApp team. While our algorithms underpin our key advantage, these deals required alignment on product integration, regulatory, clinical and commercial aspects.

In many countries, obtaining reimbursement is a key driver for adoption. It is certainly a challenge in the Australian market. As part of our path to obtaining reimbursement, this year we signed an agreement with Doctors on Demand, a leading Australia telehealth company. This agreement is not only with a well-respected partner with several major Australian corporates as customers (i.e., not wholly dependent on government reimbursement) but will also provide us with valuable realworld data to support our evidence base for future reimbursement submissions.

Low and middle-income countries bear a disproportionally high burden of the global morbidity and mortality caused by respiratory disease. ResApp was founded on Assoc. Prof. Abeyratne's research which was funded by a Gates Foundation Grand Challenges Explorations grant. The grant was to develop a low-cost diagnostic test for childhood pneumonia, one of the biggest killers of children under five in the developing world. We continue this focus, and this year signed a distribution agreement with Ilara Health in Kenya. We are excited to report very positive feedback from Ilara's customers and expect to see growth in use over the coming months.

One of the most significant deals that ResApp achieved during the last year was our licensing agreement with Janssen Pharmaceutica NV, one of the Janssen Pharmaceutical Companies of Johnson & Johnson. Janssen will use ResAppDx to assess the respiratory symptoms of a cohort of patients during a clinical trial. Not only does this deal provide an opportunity for ResAppDx to be used by eminent researchers from leading institutions across the US, Europe, South America and Asia-Pacific, it provides further validation of our technology by a global pharmaceutical company.

A driver of securing clinician adoption is publishing in peer-reviewed journals. During the year our clinical partners published several important articles in journals such as the British Journal of General Practice, Frontiers in Pediatrics and npj Digital Medicine (a Nature Partner Journal). We continue to work with our clinical partners to publish our results whenever possible.

The US is the world's largest healthcare market and we continue to make progress towards US FDA approval for our cough-based algorithms. Earlier this year we requested a Pre-Submission meeting with the FDA and, after a COVID-19-related delay, I'm pleased to confirm that we now have a meeting scheduled for December.

## **Expanding to COVID-19**

While COVID-19 is a coronavirus like the common cold, it has found a new cellular entry mechanism which allows it to access the lower respiratory tract and cause pneumonia. Early CT images from China showed a unique signature (ground glass opacity) in the lungs of many patients with COVID-19 and early research from groups at the Massachusetts Institute of Technology and the University of Cambridge suggested that cough sounds from the lungs may be able to detect if a person has a COVID-19 infection.

Earlier this year we announced our own efforts in developing a low cost, instant screening test for COVID-19 that uses coughs recorded on a smartphone. We have designed a comprehensive clinical program for the collection of the high-quality clinical data needed to develop robust and clinically accurate algorithms. We are pleased with progress to date, having recently completed recruitment in India and will soon complete recruitment in the US. The data we are capturing is of a high quality and this data, as well as our experience in being the only group who have taken a cough-based algorithm through to regulatory approval, puts us in a leading position for developing an instant, smartphone-based COVID-19 screening tool.

With the virus continuing to circulate widely and with the appearance of new variants, identifying a COVID-19 infection remains important, not only for screening individuals, but for disease surveillance (similar to how governments and health systems monitor flu through the winter flu season) and patient management (home self-isolation of those with COVID-19 to reduce spread, direction to physical healthcare facilities and advising treatment using oral antivirals if necessary). What ResApp has to offer here is potentially game-changing, the ability to screen for, at scale, individuals likely to have COVID-19.

# **Stepping into Patient Monitoring and Management**

600 million people globally live with chronic respiratory diseases such as asthma and chronic obstructive pulmonary disease (COPD). For these diseases, there is no cure. Patients and their healthcare providers must manage these diseases every day, managing the underlying condition and taking steps to prevent or treat exacerbations (or sudden deteriorations) of the disease. New technologies are just now starting to influence how these diseases are managed. Connected technologies are better able to connect patients with their healthcare providers to provide faster and more appropriate care. ResApp has an important role to play in this remote monitoring and management of patients, providing real-time, actionable information on a patient's lung health, all done remotely, all using the patient's own smartphone.

Our first steps in patient monitoring and management were through two agreements with AstraZeneca Japan. The first is providing our cough counting technology to their iDETECT lung cancer clinical study. We know that cough frequency is a key factor in determining and managing respiratory disease progression. Our cough counting smartphone app tracks cough frequency, giving researchers accurate data when remotely monitoring patients. We also partnered with

AstraZeneca on an asthma monitoring app used to assist patients in monitoring asthma symptoms in the home setting.

We are further exploring opportunities for our cough counting technology to be used in clinical trials and patient support programs and look to add further value by expanding from cough counting to cough analysis using the algorithms built for ResAppDx to help identify and manage acute exacerbations of diseases.

As we move deeper into disease monitoring and management, we will form partnerships for their path to market (distribution channel) and to collect additional longitudinal data. By longitudinal data, we mean collecting audio and clinical data from patients at multiple points in time as the disease progresses.

Our partnership with Carepath is a great example. Carepath's NELA device, which is similar to a Google Nest or Amazon Echo smart speaker, is designed to monitor patients in their own home. Integrating ResAppDx into the platform allows clinicians to remotely assess the respiratory symptoms of their patients. Alongside a clinical pilot in COPD patients, we will collect longitudinal data for us to improve and expand our algorithms for the management of COPD. Carepath's novel hardware is also an opportunity to collect data passively, opening up the potential to passively monitor patients using smart speakers and the like.

We have also built longitudinal data collection into our COVID-19 studies. Both our US and Indian studies are collecting longitudinal data from patients. This will allow us to monitor disease progression for the first time. We will be able to look for changes in disease, such as the worsening of symptoms, the development of pneumonia and hospitalisation. Through cough analysis, we may be able to identify these changes, or potentially even predict them.

## SleepCheck

The US is an important market for SleepCheck. 42 million American adults suffer from sleep disordered breathing, and three in ten men and almost one in five women have sleep apnoea. Up to 75% of these cases are undiagnosed. Sleep testing services in the US is a multi-billion dollar market, with home sleep testing being quickly adopted by insurance providers. FDA clearance is our gateway to access the US market and our 510(k) submission is the first step in the review process with the FDA.

Outside the US we see consistent monthly direct-to-consumer downloads of SleepCheck and are exploring potential partnerships with sleep-related companies to significantly increase our return.

## **Building Value**

Earlier this month I was invited by AstraZeneca to present at an international respiratory event at World Expo 2020 Dubai (which was held in 2021-2022 due to COVID-19). This event brought together leading scientific organisations, healthcare leaders and government policymakers to discuss key challenges for respiratory health reform post-pandemic. It was an honour to present at the event and speak about ResApp's vision for the future of respiratory disease diagnosis and management. My key message was how our technology had the opportunity to provide high quality healthcare to everybody, no matter where they are in the world.

I would like to express my gratitude and appreciation for the employees of ResApp. Our small team of dedicated people have achieved a great deal. Our technology is world-leading, our products are unique and built upon a solid regulatory and clinical base. These foundations have allowed us to secure partnerships with leading organisations that will see our technology in the hands of patients and clinicians worldwide. I believe this is how we will build lasting value for our shareholders.

We again thank our shareholders for their longstanding support and belief in our team and our company.

We are excited about what's next.

Sincerely,

Chief Executive Officer and Managing Director ResApp Health Limited

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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>.

#### 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.