



26 November 2020

Dear fellow Shareholders,

2020 has been another successful year for ResApp. Against the background of a global pandemic, we have made substantial progress in the commercialisation of both ResAppDx and SleepCheck.

As the world dealt with the outbreak of COVID-19, the digital transformation of healthcare greatly accelerated. Emerging sectors such as telehealth and remote monitoring have witnessed significant advancements almost overnight. Telehealth providers in the United States (US) have seen up to 175 times the number of telehealth consultations this year when compared to previous years. In the United Kingdom (UK), up to 75% of all general practitioner visits in April were carried out virtually, compared to 25% pre-pandemic.

While we are excited about the remarkable progress that has been made in vaccine development, we are confident that adoption of digital healthcare will continue.

A recent report by McKinsey suggested that 76% of people are interested in telehealth and estimated that approximately \$250 billion of US health spend could be virtualised. It is this combination of patient convenience and cost savings that will continue to drive the adoption of telehealth. ResApp is very well positioned in this space, as our technology plays a unique role in helping maintain the high quality of care demanded by patients and their doctors and, as a software solution, is easily deployed and highly scalable.

We have pioneered the use of audio as a biomarker for lung health, and we continue to lead the world in this area. Our team has developed world-leading expertise in audio analysis and machine learning as well as the crucial clinical and regulatory processes needed to bring digital health products to market. There are very few organisations in the world with this level of digital health expertise. The products ResApp has created and continue to develop provide multiple, large-scale commercial opportunities and have the potential to improve the health of billions of people globally.

### **Key Partnerships in Telehealth**

Since inception, our strategy for commercialising ResAppDx has been centred around partnerships with telehealth providers. Our unique value proposition is in providing telehealth clinicians with the only regulatory approved method of accurately assessing and diagnosing patients who present with respiratory symptoms. This closes the gap between physical and virtual by facilitating clinicians' ability to deliver the same level of care that they would during an in-person visit.

We have established partnerships with leading Australian telehealth providers by launching on the CoviU and Phenix Health telehealth platforms in mid 2020. While uptake of ResAppDx in Australia has been gradual, largely due to unique conditions surrounding the pandemic, these partnerships demonstrate to leading telehealth companies globally that ResApp has the ability and know-how to integrate ResAppDx into their systems and platforms.

Our team has managed to overcome the challenges associated with business development initiatives in Europe brought on by the pandemic and secured an important partnership with Medgate AG. Founded almost 20 years ago in Switzerland, Medgate is a well-known and respected telemedicine company and operates Europe's largest telemedical centre. We are working closely with the Medgate team to integrate ResAppDx and we expect to begin a three-month pilot in early 2021. This is a major achievement and will provide ResApp with another opportunity to progress the uptake of ResAppDx.

We recently partnered with Workplace Medicine Australia (WMA) to integrate ResAppDx into their Medetective telehealth application. The partnership with WMA offers ResApp access to the workplace health sector – an area of healthcare which is growing in Australia and a market segment that is already a major part of healthcare in many overseas countries.

We received feedback from the US Food and Drug Administration (FDA) on ResAppDx in March 2020. The FDA had not approved our request for De Novo classification of ResAppDx and required additional information to demonstrate that the probable benefits outweighed the probable risks. During the year we have been working with our regulatory consultants to formulate a detailed response to the FDA's comments and are confident that we have identified a path forward. Our next step will be a Pre-Submission meeting with the FDA to discuss this response and we expect to submit a meeting request with the FDA shortly.

### **Launch of SleepCheck in 36 Countries**

After several years of research and development we launched SleepCheck for iPhones in 2020. SleepCheck is the world's first direct-to-consumer sleep apnoea screening app. SleepCheck lowers the barriers to sleep apnoea diagnosis – it's a simple online purchase and download from the Apple App Store, there are no wires, no attachments, and users sleep comfortably in their own bed. Our regulatory team successfully achieved CE marking and TGA approval for SleepCheck as a Class I medical device.

Alongside the SleepCheck product launch we launched the "Sleepy Town" marketing campaign. The campaign raised awareness regarding the importance of screening for sleep apnoea and broadcast the introduction of SleepCheck. We worked closely with the team from Isobar as well as the residents of Tuross Heads, NSW, to create a short film titled "The Sleepy Town with a Snoring Problem", highlighting the detrimental effect that snoring has on partners and how SleepCheck can advise whether snoring could be a sign of sleep apnoea. The initial campaign was run across digital and social media platforms.

The SleepCheck launch was also featured in major media outlets, with over 100 pieces of coverage across TV, radio, print and online.

At the end of the second quarter of FY2021 we were pleased to announce that 3,946 downloads of SleepCheck had occurred by that date.

To underpin additional growth, we have secured two key partnerships. Our first is with Diabetes Queensland, which will drive awareness of SleepCheck among people living with diabetes, who are an at-risk population. It is estimated that up to 80% of diabetics experience sleep apnoea. Our second partnership, with HealthEngine, provides users a quick and easy way to book an appointment with their general practitioner after completing the SleepCheck test.

With 42 million Americans suffering from sleep apnoea, the US is an important market for SleepCheck. Following a Pre-Submission meeting with the FDA, we are pleased to have identified a clear path to secure regulatory approval. We plan to initially file as a prescription only (Rx only) device via a 510(k) submission, and then file an additional over-the-counter (OTC) submission. We are progressing quickly and expect to lodge a 510(k) submission in Q3 FY2021.

### **Expanding the Opportunity to Android Devices**

Android devices are a large portion of the global smartphone market and the launch of ResAppDx for Android marked a major technical milestone for ResApp and highlighted our innovative approach to digital health.

Developing an Android solution was a significant technical challenge as these devices have a multitude of different form factors and microphones. To overcome this challenge our team created a number of new, proprietary testing procedures and algorithm improvements.

ResAppDx is now available on the first set of Samsung devices (Galaxy S9, S10 and S20) which are among the most popular Android devices in Australia and Europe. Work to validate other Android devices is ongoing, with additional launches expected in the coming months.

### **Laying the Foundations for Future Growth**

A key component to our technology is the ability to identify coughs from background noises in everyday settings. ResAppDx then analyses these coughs to differentially diagnose disease but coughs themselves are also important markers of disease progression. We are pleased to note that our cough identification algorithms will be deployed via a new app to be used by AstraZeneca in a clinical study of lung cancer patients. By measuring cough frequency, AstraZeneca will be able to monitor the progress of study participants. Projects such as this deliver valuable insights and support our efforts to explore new opportunities. The agreement with AstraZeneca also provides considerable validation of our offering by one of the world's leading biopharmaceutical companies.

The COVID-19 pandemic has seen increased consumer empowerment in healthcare, with consumers gaining more confidence in the use of technology for monitoring health. Since the founding of ResApp, we have pursued the option of bringing ResAppDx directly to consumers. This inspired our efforts under the Startup Creosphere Digital Health Program with Sanofi (now completed) and our subsequent collaboration with RB, a global consumer goods company. Building an app for consumers that identifies respiratory conditions involves a number of technical, regulatory and commercial challenges and we have been working closely with RB to address these.

Leveraging the funding for initial technology development received by Dr Abeyratne from the Bill and Melinda Gates Foundation, we have continued to focus on deploying our technology in low- and middle-income countries. This year, we have been working with Ilara Health to conduct an evaluation of ResAppDx in Kenya. The evaluation is now underway in five medical facilities in the country and we are looking forward to receiving the results early in 2021.

Whilst telehealth provides a unique commercial angle, ResAppDx also offers significant benefits when used to triage patients in over-burdened clinics. To unlock additional opportunities, we are working on our own ruggedised handheld devices for use in these environments and also working with a group of highly regarded teaching hospitals in the UK to perform health-economic studies.

These studies aim to demonstrate and quantify a reduction in costs and time to treatment along with improved patient flow, which have all been shown to decrease accident and emergency (A&E) department congestion, give patients a better experience and ease pressure on staff. A similar study is planned in Germany. While these studies are currently on hold due to circumstances related to COVID-19, we look forward to progressing them once the demand on A&E departments has subsided.

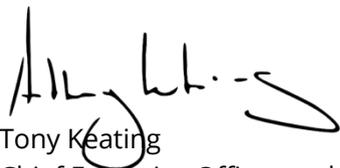
### **Our Long-term Vision**

The founding team started ResApp just over five years ago with the vision that we could provide clinical quality diagnostic tests and management tools to healthcare providers and consumers. By delivering digital solutions, our goal is to significantly enhance the ways in which respiratory diseases are diagnosed and managed at scale. So far, we have made significant progress towards that goal, having taken a technology from a university lab into the real world in a very short timeframe. We have built high-quality products that have been through rigorous clinical and regulatory tests, that are now directly benefiting healthcare professionals and consumers.

All of the commercial deals that we have announced recently result from years of dedicated work by our team. Many different people at ResApp have contributed to these achievements, from board members, both past and present, to members of staff and multiple individuals behind the scenes. Their efforts have yielded stellar technologies and unique products, built upon a solid regulatory and clinical base, and with our recent partnerships we have begun building a strong commercial base from which to scale our business.

We extend our thanks to our shareholders for their continued support and belief in our company. Our team is excited about the future, and we look forward to sharing more news with you shortly.

Sincerely,



Tony Keating  
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 [www.resapphealth.com.au](http://www.resapphealth.com.au).

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