

### **Quarterly Activities Report**

For the period ending 31 March 2021

- Leading telehealth provider, Medgate AG commences three-month pilot trial of ResAppDx across telemedicine services in Switzerland
- Smartphone-based COVID-19 screening test under development with clinical study to explore relationship between cough sounds and COVID-19
- Second licensing agreement secured with AstraZeneca Japan for use of ResApp's cough counting technology in asthma patient support program
- CE Mark and TGA clearance achieved for wearable device an easily worn, clip-on, unobtrusive platform, for continuous 24-hour cough monitoring
- Progress made towards US FDA clearances for SleepCheck and prescription-only software as a medical device application to detect lower respiratory tract illness
- Experienced healthcare executive Mike Connell appointed as VP, Commercial to drive partnership and growth strategy

**Brisbane, Australia, 30 April 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 provide an activities update for the three month period ended 31 March 2021 ("Q3 FY2021").

#### **OPERATIONAL HIGHLIGHTS**

#### ACUTE RESPIRATORY DIAGNOSIS

#### Medgate AG ("Medgate") commences European ResAppDx trial

In early March, Medgate commenced a three-month pilot trial of ResApp's smartphone-based respiratory test, ResAppDx across its telemedicine services in Switzerland.

Medgate is a leading provider of telehealth services and since 2000 has operated the largest telemedical centre run by doctors in Europe. The group employs over 500 people worldwide including over 200 physicians.

During the pilot, ResApp and Medgate will jointly assess the impact of ResAppDx on Medgate's telehealth services though a range of key performance indicators. Both parties are also in broader commercial negotiations pending a successful trial outcome.



ResApp has continued commercial discussions with Ilara Health, a Kenya-based health technology company, to progress the launch of ResAppDx to medical facilities and clinics in Kenya. Negotiations follow Ilara's three-month evaluation of ResAppDx at five medical facilities in Kenya.

Discussions have advanced favourably, and the company expects that it will be able to provide shareholders with a more detailed update shortly.

# Pre-Submission package lodged with US FDA for prescription-only software as a medical device to detect lower respiratory tract illness

In February, ResApp filed a Pre-Submission package with the United States (US) Food and Drug Administration (FDA) and requested a meeting with the agency to progress the potential clearance of a prescription-only software as a medical device application to detect lower respiratory tract illness in children and adults.

The Pre-Submission program provides ResApp the opportunity to obtain targeted feedback from the FDA in response to questions related to data requirements and marketing applications prior to a pre-market submission.

#### **COVID-19 SCREENING**

#### Smartphone-based COVID-19 screening test in development

During the quarter, ResApp made progress to commence a US-based clinical study to explore the relationship between cough and SARS-CoV2 ("COVID-19") infection and entered into an engagement with leading US clinical-grade testing company, Phosphorus.

The aim of the pilot study is to secure data to train an algorithm to identify COVID-19 through cough sounds recorded on a smartphone, using Phosphorus' gold-standard at-home saliva-based real-time Polymerase Chain Reaction (rt-PCR) pathology test as a reference standard.

ResApp has recently achieved Institutional Review Board (IRB) approval for the study. Study start-up is now underway and patient recruitment is expected to begin shortly.

The ability to identify COVID-19 will considerably strengthen ResApp's offering and applicability within health systems and potentially broader settings where rapid, mass screening would be of considerable value.

#### MEASURING LUNG HEALTH THROUGH OBJECTIVE COUGH COUNTING

#### Cough counting SDK licence granted to AstraZeneca for asthma patient support program

In March, ResApp secured a one year, non-exclusive licensing agreement with AstraZeneca K.K. ("AstraZeneca"), the Japanese subsidiary of global biopharmaceutical company AstraZeneca PLC., to license its cough counting technology for use in a program to support asthma patients. This is the second agreement the company has entered into with AstraZeneca and provides further validation from an industry-leading pharmaceutical company.



ResApp is currently working with AstraZeneca on integration of the software development kit (SDK) into AstraZeneca's direct-to-consumer asthma management smartphone application, refining it to the group's specifications for use in the Japanese market.

#### CE Mark and TGA clearance achieved for wearable device

ResApp achieved CE Mark certification and Australian Therapeutic Goods Administration (TGA) clearance for its wearable device as a Class I medical device accessory in March, allowing the company to progress the manufacture and sale of the product in Europe and Australia.

ResApp's wearable device is an easily worn, clip-on, unobtrusive platform, which allows for continuous 24-hour patient monitoring using cough audio. It has broad applicability. ResApp will initially focus on clinical trial settings to measure cough frequency, which is one of the major indicators of disease progression.

#### **SLEEP APNOEA SCREENING**

#### Progress towards potential US FDA clearance for SleepCheck

To progress the expansion and availability of SleepCheck into additional markets, the company held a pre-submission meeting with the US FDA in Q2 FY2021. Following that meeting ResApp elected to pursue 510(k) clearance in the US as a prescription-only device.

During the quarter, ResApp completed a human factor study and a follow-up meeting with the agency to progress the clearance of SleepCheck. ResApp is now finalising the 510(k) submission, which is expected to be made this quarter.

#### COMPANY

#### Appointment of Mr Mike Connell as Vice President (VP), Commercial

Mr Connell is a leading executive with extensive experience in sales, marketing and strategy, focused on the pharmaceuticals, health insurance and fast-moving consumer goods (FMCG) sectors.

Mr Connell has over a decade of healthcare related experience and has held longstanding positions with GlaxoSmithKline (GSK). Most recently, Mr Connell was General Manager, Corporate Portfolio at Medibank, and was responsible for corporate health partnerships.

As VP, Commercial, Mr Connell will pursue global commercial activities and progress the company's growth strategy. ResApp is confident that his deep sector understanding and established networks will give the company access to multiple opportunities over the coming months.

#### European patent position strengthened

During the quarter, the European Patent Office issued a Notice of Allowance for ResApp's patent titled: "Methods and apparatus for cough detection in background noise environments." The patent covers the use of machine learning audio processing technique for identifying cough sounds in environments with significant background noise. The technology covered in the patent is currently used in ResAppDx and ResApp's cough counting applications.



#### **THIRD QUARTER FINANCIAL RESULTS**

Receipts from customers for the quarter totalled \$48,000 (Q2 FY2021: \$42,000), which comprised of advanced payments from AstraZeneca and payments from Apple and Google for SleepCheck downloads. The company also received \$859,000 in Government grants and tax incentives, this comprised of an R&D tax rebate, an Export Market Development Grant and JobKeeper related payments.

Overall cash decrease was \$1,017,000 (Q2 FY2021: \$1,589,000), with net cash used in operating activities totalling \$957,000 (Q2 FY2021: \$1,541,000). Research and development payments increased to \$541,000 (Q2 FY2021: \$310,000) due to costs related to the SleepCheck human factor study and the start-up of the smartphone-based COVID-19 screening test study. Advertising and marketing costs decreased to \$125,000 (Q2 FY2021: \$427,000). Staff costs slightly increased to \$947,000 (Q2 FY2021: \$853,000). The company made payments of \$139,000 to directors during the period (\$69,000 for non-executive director fees and \$70,000 for Managing Director remuneration).

ResApp retained a cash balance of \$3.2m at the end of the quarter, which was strengthened following period end. The Company has the necessary financial flexibility to progress a number of near-term growth initiatives.

#### ResApp secures firm commitments to raise \$5.5m

In April, ResApp received commitments from institutional, professional and sophisticated investors to raise \$5.5m (before costs) through the issue of 94,827,588 new fully paid ordinary shares at an issue price of 5.8 cents per share. Shares were issued under the company's existing placement capacity under ASX Listing Rule 7.1 on 19 April 2021.

#### **MANAGEMENT COMMENTARY**

**CEO and Managing Director Dr Tony Keating said:** *"ResApp has made strong progress during the quarter across all key focus areas. We have cemented a number of partnerships and progressed regulatory approval processes, which have the potential to unlock a number of opportunities.* 

"During the current period, we expect to secure agreements with new partners to drive product uptake, as well as achieve a number of key milestones. These include first patient recruitment for the clinical study into the relationship between cough sounds and COVID-19 which is an important step in the development of a rapid COVID-19 screening test that only requires a smartphone, the submission of a 510(k) for SleepCheck clearance in the US, advancements with Medgate and a potential agreement with Ilara Health to enter the African market.

"Following the appointment of Mike Connell as VP Commercial, we have witnessed our pipeline of possible partnerships build. We look forward to capitalising on these new opportunities over the coming months to unlock value for shareholders."



#### **CONFERENCE CALL DETAILS**

Shareholders are invited to join a conference call hosted by Managing Director and CEO, Dr Tony Keating at 10:00am Australian Eastern Standard Time (AEST) today. Shareholders can preregister for the call by following the link below. Registered participants will receive a calendar notification with dial-in details and a PIN to access the call.

https://s1.c-conf.com/diamondpass/10013791-o3puho.html

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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

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

## Appendix 4C

### Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity				
ResApp Health Limited				
ABN	Quarter ended ("current quarter")			
51 094 468 318	31 March 2021			

Consolidated statement of cash flows		onsolidated statement of cash flows Current quarter \$A'000	
1.	Cash flows from operating activities		
1.1	Receipts from customers	48	93
1.2	Payments for		
	(a) research and development	(541)	(1,228)
	<ul> <li>(b) product manufacturing and operating costs</li> </ul>	-	-
	(c) advertising and marketing	(125)	(694)
	(d) leased assets	-	-
	(e) staff costs	(947)	(2,615)
	(f) administration and corporate costs	(253)	(722)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	2	17
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	859	1,205
1.8	Other (provide details if material)	-	-
1.9	Net cash from / (used in) operating activities	(957)	(3,944)

2.	Ca	sh flows from investing activities	
2.1	Payments to acquire or for:		
	(a)	entities	-
	(b)	businesses	-
	(c)	property, plant and equipment	(23)
	(d)	investments	-
	(e)	intellectual property	-
	(f)	other non-current assets	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 months) \$A'000
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	
2.5	Other (provide details if material)		
2.6	Net cash from / (used in) investing activities	(23)	(44)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	_	-
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	1,525
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Payment of lease liability	(37)	(111)
3.10	Net cash from / (used in) financing activities	(37)	1,414

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	4,218	5,775
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(957)	(3,944)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(23)	(44)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(37)	1,414
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	3,201	3,201

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter \$A'000	Previous quarter \$A'000
5.1	Bank balances	3,201	4,218
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	3,201	4,218

6.	Payments to related parties of the entity and their associates	Current quarter \$A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	(139)
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
	f any amounts are shown in items 6.1 or 6.2, your quarterly activity report must includ ation for, such payments.	le a description of, and an
ltem 6.	1 above includes Directors fees and salary (including superannuation) for Managing I	Director.

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7.

<b>Financing facilities</b> Note: the term "facility' includes all forms of financing arrangements available to the entity. Add notes as necessary for an understanding of the sources of finance available to the entity.	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000	
Loan facilities	-	-	
Credit standby arrangements	-	-	
Other (please specify)	-	-	
Total financing facilities	-	-	
Unused financing facilities available at qu	arter end	-	
Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.			

8.	Estim	ated cash available for future operating activities	\$A'000	
8.1	Net ca	sh from / (used in) operating activities (item 1.9)	(957)	
8.2	Cash a	and cash equivalents at quarter end (item 4.6)	3,201	
8.3	Unuse	d finance facilities available at quarter end (item 7.5)	-	
8.4	Total a	vailable funding (item 8.2 + item 8.3)	3,201	
8.5	Estima item 8	ated quarters of funding available (item 8.4 divided by .1)	3	
		Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.		
8.6	If item	If item 8.5 is less than 2 quarters, please provide answers to the following questions:		
	8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?			
	Answe	er:		
	8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?			
	Answe	er:		
	8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?			
	Answe	er:		
	Note: w	here item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 abov	e must be answered.	

#### **Compliance statement**

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

30 April 2021

Date:

#### **Tony Keating**

Authorised by:		
	(Name of body or officer authorising release – see note 4	ł)

#### Notes

- This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
- 2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, AASB 107: Statement of Cash Flows apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
- 3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.
- 4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee – eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
- 5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's Corporate Governance Principles and Recommendations, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.