

## Quarterly Activities Report

For the period ending 30 June 2022

- **New ResAppDx customer agreement with Dartford and Gravesham NHS Trust (UK)**
- **One-year extension to Medgate licence agreement with expansion into Germany in CY2023**
- **Validation study of COVID-19 algorithm showed 84% sensitivity and 58% specificity, substantially lower than pilot study**
- **US FDA 510(k) clearance for SleepCheckRx**
- **Customer receipts for the quarter, including \$4,056,000 received from Pfizer under the research and development licence agreement, increased to \$4,207,000 (Q3: \$178,000)**

**\*\* NOTE: ResApp advises that the proposed conference call to be hosted by Tony Keating, CEO and Managing Director on Wednesday, 27 July 2022 at 10:00am Australian Eastern Standard Time (AEST), has been postponed. The company will provide an update on a new date and time for the call in a future announcement.**

**Brisbane, Australia, 27 July 2022** – 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 30 June 2022 (“Q4 FY2022”).

### **OPERATIONAL HIGHLIGHTS**

#### **ACUTE RESPIRATORY DIAGNOSIS**

##### **Continued broader use of ResAppDx**

In April, ResApp signed a one-year agreement with the Dartford and Gravesham National Health Service (NHS) Trust to pilot ResAppDx across its four hospitals. The Trust provides a comprehensive range of acute services and some community services to over 500,000 people in Kent, United Kingdom. Initial use will be to assess patients who present to the Trust’s respiratory outpatient clinic before expanding use into other areas of the hospital and potentially into primary care. The pilot is expected to commence in the third quarter of calendar year 2022.

After the end of the quarter, ResApp signed a twelve-month extension to its licence agreement with Medgate. Medgate is a leading provider of telehealth services in Europe and operates Europe’s largest telemedical centre run by doctors. Medgate also plans to expand the use of ResAppDx across additional patient journeys and will expand use into Germany in calendar year 2023.

### **ResAppDx US FDA update**

After meeting with the US Food and Drug Administration (FDA) in January, ResApp expects to continue to engage with the FDA through additional pre-submission meetings in the second half of calendar year 2022 to progress clearance of a prescription-only software as medical device application to detect lower respiratory tract illness in children and adults. During the quarter, the company continued to work with its advisors to prepare pre-submission meeting request documents.

### **COVID-19 RESEARCH PROGRAM**

#### **Results from validation study of COVID-19 algorithms**

In March, ResApp 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, ResApp's screening test was found to correctly detect COVID-19 in 92% of people with infection. The test was found to identify patients who don't have COVID-19 with 80% specificity. This reported performance was obtained using K-fold cross-validation to provide an estimate of performance on unseen data.

During the quarter, ResApp progressed a validation study of the algorithms by recruiting 1,566 additional patients in India and the US. In June, ResApp announced the results from the validation study which showed that ResApp's COVID-19 algorithm achieved a sensitivity of 84% and a specificity of 58%, significantly lower than the results of ResApp's cross-validation results from its pilot trial and not commercially viable.

ResApp is investigating a number of factors that could have caused the poor results, including the ever-changing nature of COVID-19 variants, changes in background diseases seen in patients presenting for COVID-19 testing as well as confounding factors and biases in the dataset used to train the algorithms.

While ResApp remains confident that COVID-19 has a unique signature that can be found in the audio of cough sounds, further research will be needed to increase the performance of the algorithms to commercially viable levels. As part of this research, ResApp will need to recruit additional patients to build a larger dataset to both train and validate algorithm options.

### **SLEEP APNOEA SCREENING**

#### **SleepCheckRx receives US FDA 510(k) clearance**

In July, ResApp received notice from the US Food and Drug Administration (FDA) that SleepCheckRx, its prescription-only smartphone-based sleep test, had received 510(k) clearance. Gaining this clearance enables ResApp to commercially market the test in the US.

Sleep apnoea is the most common sleep breathing disorder and affects more than three in every ten men and nearly two in every ten women. Studies have shown that up to 80% of people with sleep apnoea are undiagnosed and untreated. SleepCheckRx offers a low cost and easy to use way for clinicians to screen their patients for sleep apnoea.



SleepCheckRx will be made available to patients via a prescription from their healthcare provider. Patients will be provided with a specific code allowing them to download SleepCheckRx from the App Store, with their results uploaded to a healthcare provider portal. SleepCheckRx is cleared for use on Apple iPhones and ResApp plans to solicit 510(k) clearance for Android devices in the future.

ResApp will now need to invest in the sales and marketing infrastructure needed to launch SleepCheckRx in the US with a strategy of targeting employers, commercial health plans and sleep clinics.

## **SECOND QUARTER FINANCIAL RESULTS**

Receipts from customers for the quarter totalled \$4,207,000 (Q3: \$178,000), driven by \$4,056,000 of receipts received under the Pfizer research and development licence agreement. Other customer receipts related to payments from customers for SleepCheck downloads and ResAppDx use, as well as additional advanced payments from Janssen.

Research and development payments increased to \$1,625,000 (Q3: \$410,000) due to the additional costs for recruitment in US and India COVID-19 studies during the quarter. Advertising and marketing costs decreased to \$55,000 (Q3: \$70,000). Staff costs remained approximately constant at \$1,050,000 (Q3: \$1,018,000). Administration and corporate costs increased to \$766,000 (Q3: \$257,000) due to costs associated with recent corporate and transactional activity.

The company paid \$150,000 in US withholding tax on the upfront payment from Pfizer under the research and development licence agreement.

The company made payments of \$177,000 to directors during the period (\$64,000 for non-executive director fees and \$113,000 for executive director fees).

Overall cash increase was \$622,000 (Q3: decrease \$1,706,000), with net cash from operating activities totalling \$636,000 (Q3: net cash used in operating activities \$1,577,000).

ResApp retained a cash balance of \$2.3 million at the end of the quarter.

## **MANAGEMENT COMMENTARY**

**CEO and Managing Director Dr Tony Keating said:** *"We continue to see good progress in getting ResAppDx into the hands of clinicians and patients globally. We are excited about working with the innovative team at the Dartford and Gravesham NHS Trust to gain real-world experience of ResAppDx use within the NHS. We are also delighted that Medgate has renewed their licence agreement and were pleased to announce two important growth initiatives with Medgate: integration of ResAppDx into additional patient journeys and expansion of ResAppDx into their German business in 2023.*

*"Achieving our first US FDA clearance is a milestone achievement for the company. We first announced our sleep apnoea screening test four years ago, after a successful pilot study where Dr Philip Currie and Dr Ivan Ling of Cardio Respiratory Sleep (CRS) recruited patients in Perth, Western Australia. Since then, we have run a successful prospective clinical trial, obtained CE Mark and ARTG listing, and launched*



*SleepCheck on the App Store and Google Play in 36 countries. With US FDA clearance, we now look forward to launching in the US which represents a very large market opportunity.*

*"The results from the validation study of our COVID-19 algorithms were below our expectations and our team has additional research to do to improve their performance and robustness before they are ready for further validation testing, regulatory submission, and commercial use. We certainly see a future for cough-audio-based detection of COVID-19 and our team is working hard to investigate and improve our algorithms, but these results underscore the considerable work, challenge and cost of bringing this to market.*

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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 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; SleepCheckRx, a prescription-only smartphone application that screens adults for moderate to severe sleep apnoea; and SleepCheck, a smartphone application which allows consumers to self-assess their risk of sleep apnoea. For more information, please visit [www.resapphealth.com.au](http://www.resapphealth.com.au).

### **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**
**51 094 468 318**
**Quarter ended ("current quarter")**
**30 June 2022**

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (12 months) \$A'000</b>
<b>1.</b>	<b>Cash flows from operating activities</b>		
1.1	Receipts from customers	4,207	4,516
1.2	Payments for		
	(a) research and development	(1,625)	(3,290)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(55)	(214)
	(d) leased assets	-	-
	(e) staff costs	(1,050)	(4,118)
	(f) administration and corporate costs	(766)	(1,656)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	-	4
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	(150)	(150)
1.7	Government grants and tax incentives	75	894
1.8	Other (provide details if material)	-	-
<b>1.9</b>	<b>Net cash from / (used in) operating activities</b>	<b>636</b>	<b>(4,014)</b>
<b>2.</b>	<b>Cash flows from investing activities</b>		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(8)	(30)
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	(7)	(138)

Appendix 4C  
Quarterly cash flow report for entities subject to Listing Rule 4.7B

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (12 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)	-	-
<b>2.6 Net cash from / (used in) investing activities</b>	<b>(15)</b>	<b>(168)</b>

<b>3. Cash flows from financing activities</b>		
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	40	40
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	(39)	(155)
<b>3.10 Net cash from / (used in) financing activities</b>	<b>1</b>	<b>(115)</b>

<b>4. Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1 Cash and cash equivalents at beginning of period	1,668	6,587
4.2 Net cash from / (used in) operating activities (item 1.9 above)	636	(4,014)
4.3 Net cash from / (used in) investing activities (item 2.6 above)	(15)	(168)

Appendix 4C  
Quarterly cash flow report for entities subject to Listing Rule 4.7B

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (12 months) \$A'000</b>
4.4	Net cash from / (used in) financing activities (item 3.10 above)	1	(115)
4.5	Effect of movement in exchange rates on cash held	-	-
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>2,290</b>	<b>2,290</b>

<b>5.</b>	<b>Reconciliation of cash and cash equivalents</b> at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	<b>Current quarter \$A'000</b>	<b>Previous quarter \$A'000</b>
5.1	Bank balances	2,290	1,668
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>2,290</b>	<b>1,668</b>

<b>6.</b>	<b>Payments to related parties of the entity and their associates</b>	<b>Current quarter \$A'000</b>
6.1	Aggregate amount of payments to related parties and their associates included in item 1	(177)
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
<p><i>Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.</i></p> <p>Item 6.1 above includes Directors fees and salaries (including superannuation) for Managing Director and Executive Director, Corporate Affairs.</p>		

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

<b>7. Financing facilities</b>	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
<i>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.</i>		
7.1 Loan facilities	-	-
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	-	-
7.4 <b>Total financing facilities</b>	-	-
7.5 <b>Unused financing facilities available at quarter end</b>		-
7.6 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.		

<b>8. Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1 Net cash from / (used in) operating activities (item 1.9)	636
8.2 Cash and cash equivalents at quarter end (item 4.6)	2,290
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	2,290
8.5 <b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	<b>N/A</b>
<i>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.</i>	
8.6 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?	
Answer:	
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?	
Answer:	
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?	
Answer:	
<i>Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.</i>	



**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.

27 July 2022

Date: .....

Tony Keating

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

**Notes**

1. 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.