

## APPENDIX 4C – Q1 FY20/21 QUARTERLY REPORT

Resonance Health Limited (ASX: RHT) ("Resonance Health" or "Company") – Quarterly Report for the period ended 31 December 2020.

Summary of Business Performance for the December quarter:

Cash on hand at 31 December 2020 of \$8.1m, an increase of \$715K over 30 September 2020.

Cash receipts from customers of \$1m, an increase of 6% over the September 2020 quarter and an increase of 16 % over the December 2019 quarter.

R&D tax incentive refund of \$242K received on 15 December 2020 for eligible R&D work performed in FY 19/20.





## **R&D Update for the December quarter:**

### ALERTE-PE:

As part of the artificial intelligence ("AI") product workstream, work has progressed on ALERT-PE, a software tool for the automated review of chest computed tomography ("CT") scans of patients with suspected pulmonary embolism ("PE"), a potentially life-threatening condition (see ASX announcement dated 6 October 2020). PE is part of the venous thromboembolism ("VTE") spectrum, which ranges from asymptomatic deep vein thrombosis ("DVT") to fatal PE, and is a blockage of the pulmonary arteries in the lungs caused by blood clots<sup>1</sup>. With at least 650,000 cases occurring annually, PE is the third most common cause of death in hospitalised patients and autopsy studies have shown that



approximately 60% of patients who have died in hospital had PE, with the diagnosis having been missed in up to 70% of the cases<sup>2</sup>. It is intended that ALERT-PE may be able to triage images for trained radiologists during their highly time-sensitive assessment of CT images in patients with suspected PE. The Company considers that ALERT-PE is able to perform as an Al-based radiological computer-assisted triage and notification software for PE.

 A pre-submission meeting was held with the US Food and Drug Administration ("FDA") in November 2020 for ALERT-PE, as previously announced (see ASX announcement dated 6 October 2020, 'R&D Update: New Pulmonary Embolism Al Solution Developed'). Following the meeting, FDA recommendations have been reviewed and work is being finalised for the next steps required for the validation of performance of the tool.

HEPAFAT-AI:

- HepaFat-AI received 510(k) regulatory clearance from the FDA on 9 December 2020 (see ASX announcement dated 9 December 2020). HepaFat-AI is a medical device software that is fully automated and uses AI to assess liver fat. It is estimated that 24-30% of the global population has Non-Alcoholic Fatty Liver Disease ("NAFLD"), which equates to 1.8-2.3 billion people<sup>1</sup>. Of these, it is estimated that 20%, or up to 468 million people, will also develop non-alcoholic steatohepatitis ("NASH"), the most severe form of NAFLD where inflammation can cause liver damage and fibrosis. HepaFat-AI assesses and reports the volumetric liver fat fraction ("VLFF"), proton density fat fraction ("PDFF"), and steatosis grade in individuals with confirmed or suspected fatty liver disease. HepaFat-AI is the only MRI-based method capable of reporting a steatosis grading. Dr Martin Blake, Chairman of RHT, said of HepaFat-AI's recent 510(k) FDA regulatory clearance: "This is a great milestone in the Company's history and a magnificent achievement in the field of quantitative MRI". The 510(k) FDA clearance allows Resonance Health to market HepaFat-AI for commercial distribution in the United States of America.
- HepaFat-AI is also now available for distribution and promotion by Blackford Analysis Inc. (formerly Blackford Analysis Limited) ("Blackford") under the Alliance Partner Agreement entered into between the Company and Blackford in 2018 (see ASX announcement dated 5 July 2018). The addition of HepaFat-AI was facilitated by an amendment to the Alliance Partner Agreement that was executed in December 2020 (see ASX announcement dated 24 December, 'HepaFat-AI Incorporated into Blackford Analysis Partner Agreement'). Product training on HepaFat-AI has since progressed as part of the Blackford onboarding process, with technical integration expected to commence shortly.
- Additional distribution channels for HepaFat-AI are being assessed by the Company.
- Work on obtaining Australian Therapeutic Goods Administration ("TGA") registration and European CE Mark for HepaFat-AI progressed substantially during the quarter, with registration expected to be complete during the March quarter.



OTHER AI PROJECTS: Using in-house and externally sourced MRI and CT datasets in various diseases and/or conditions, the Company has continued to make progress on training neural networks in assessing a number of human organs. These projects will be updated in greater detail when they are further progressed.

MOLECULAR MEDICINE:

- Work is continuing on the application of novel Antisense Oligonucleotides (ASOs) to treat liver disease, in particular, Chronic Hepatitis B (CHB). Antiviral testing of three highly active ASO sequences commenced in November with preliminary results expected within the first half of 2021. This data will be used to support claims of the Provisional Patent filing ahead of any international filings (see ASX announcement dated 25 May 2020, 'Filing of a Provisional Patent Application: "Method For Treating Liver Related Disease"').
- Recruitment of patients has commenced for a validation study aimed at confirming that novel blood biomarkers previously demonstrated to be predictive of liver iron overload in Vietnamese Thalassemia patients can similarly predict iron overload in Turkish Thalassemia patients. If there is applicability of this tool across both ethnic groups, this may assist in any subsequent regulatory filing.
- LIVER FIBROSIS PROJECT: The Company's study to investigate the ability of a novel non-invasive MRI method to assess liver fibrosis has continued to progress despite occasional delays due to COVID-19. Patient recruitment is now 70% complete and the first stage of this project is expected to be completed in the first half of 2021.

PHANTOM PRODUCTION: Production was completed on a new batch of the T1MES Cardiac T1 Mapping and ECV Phantoms. The T1 Mapping and ECV Standardization Program ("T1MES") was developed to explore T1 mapping quality assurance 1.5 and 3T across numerous CMR centres worldwide. As part of this study, Resonance Health manufactured an initial batch of ~70 phantoms in 2015 for distribution to CMR centres worldwide engaged in the cardiovascular magnetic resonance program. Resonance Health is the sole manufacturer of these phantoms and due to continued requests from customers, it is expected that the next batch of phantoms will be manufactured in mid-2021.

# Listing Rule 4.7C3

With respect to item 6 of the Appendix 4C cash flow report for the quarter, payments to related parties of approximately \$67.5K were made during the quarter. This comprised of \$45K of remuneration paid to non-executive directors, and \$22.5K for consultancy services provided by Mr. Mitchell Wells through his service company, Biggles Pty Ltd (ATF the Biggles Investment Trust). Mr. Wells is a director of the Company and is therefore a related party.

## Authorised by

This announcement has been authorised for release in accordance with the delegated authority of the Board of Directors of Resonance Health Limited.



### **About Resonance Health**

Resonance Health is an Australian healthcare company specialising in the development and delivery of noninvasive medical imaging software and services. Resonance Health has gained endorsement by leading physicians worldwide for consistently providing high quality quantitative measurements essential in the management of particular diseases. The Company's products are used globally by clinicians in the diagnosis and management of human diseases and by pharmaceutical and therapeutic companies in their clinical trials. Resonance Health's dedication to scientific rigour has enabled it to achieve regulatory clearances on a number of software products (SaMD) in the US, Europe, and Australia, including FerriSmart<sup>®</sup>, an artificial intelligence product that quantifies iron concentration in the liver. The Company has also recently received US FDA regulatory clearance for a second artificial intelligence tool, HepaFat-AI. The Company is working on several other developments including, among others, ALERTE-PE, which is an AI tool for the automated review of chest CT scans of patients with suspected pulmonary embolism.

### For further information please contact:

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- Singer, A. J., Thode, H. C., Jr, & Peacock, W. F., 4th (2016). Admission rates for emergency department patients with venous thromboembolism and estimation of the proportion of low risk pulmonary embolism patients: a US perspective. Clinical and experimental emergency medicine, 3(3), 126–131. https://doi.org/10.15441/ceem.15.0963
- 2. Ouellette, D. What percentage of hospitalized patients have pulmonary embolism (PE). <u>https://www.medscape.com/answers/300901-8452/what-percentage-of-hospitalized-patients-have-pulmonary-embolism-pe</u>
- 3. Sayiner M, Koenig A, Henry L, Younossi ZM. Epidemiology of nonalcoholic fatty liver disease and nonalcoholic steatohepatitis in the United States and the rest of the world. Clinics in Liver Disease. 2016;20:205-214

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

Name of entity			
Resonance Health Limited			
ABN Quarter ended ("current quarter")			
96 006 762 492	31 December 2020		

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
1.	Cash flows from operating activities		
1.1	Receipts from customers	1003	1944
1.2	Payments for		
	(a) research and development	(137)	(243)
	(b) product manufacturing and operating costs		
	(c) advertising and marketing	(74)	(124)
	(d) leased assets		
	(e) staff costs	(534)	(1009)
	(f) administration and corporate costs	(107)	(251)
1.3	Dividends received (see note 3)		
1.4	Interest received	1	37
1.5	Interest and other costs of finance paid		
1.6	Income taxes paid		
1.7	Government grants and tax incentives	287	535*
1.8	Other (provide details if material)		
1.9	Net cash from / (used in) operating activities	439	889

\*Includes \$176K from JobKeeper Payment, \$17.5K from OSR COVID-19 Grant, \$100K for PAYG Cashflow Boost and \$242K from R&D Tax Incentive refund for FY 2020.

	Cash flows from investing activities	
2.1	Payments to acquire:	
	(a) entities	
	(b) businesses	
	(c) property, plant and equipment	(7)
	(d) investments	
	(e) intellectual property	

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
	(f) other non-current assets		
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	(7)	(15

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	343	343
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	Other (provide details if material)		
3.10	Net cash from / (used in) financing activities	343	343

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	7393	6974
4.2	Net cash from / (used in) operating activities (item 1.9 above)	439	889
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(7)	(15)

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	343	343
4.5	Effect of movement in exchange rates on cash held	(60)	(83)
4.6	Cash and cash equivalents at end of period	8108	8108

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	8108	7393
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)	8108	7393

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	68
6.2	Aggregate amount of payments to related parties and their associates included in item 2	

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

- 7.2 Credit standby arrangements
- 7.3 Other (please specify)
- 7.4 Total financing facilities

Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000

## 7.5 Unused financing facilities available at quarter end

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.

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (Item 1.9)	439
8.2	Cash and cash equivalents at quarter end (Item 4.6)	8108
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	8108
8.5	Estimated quarters of funding available (Item 8.4 divided by Item 8.1)	18

- 8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:
  - 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: N/A

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:

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:

# **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.

### Date: 28 January 2021

Authorised by: By the Board of Directors of Resonance Health Limited

### 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.