

# **QUARTERLY ACTIVITIES & CASHFLOW REPORT**

# Highlights

Resonance

Health

- Focus on building business to drive future revenue growth, through development of global sales & marketing strategy, recruitment of high-calibre sales & marketing and technology teams, and further product development aligned to identified market opportunities
- Development and early execution of global sales and marketing strategy, based on established regulatory-approved product suite, excellent technical reputation, solid market position, and revenue base
- Key appointments including General Manager Global Sales & Marketing, and Chief Technology Officer. Recruitment of dedicated global salesforce underway with the hiring of US Sales Manager, Global Marketing Manager, and US-based Clinical Trials Specialist, together with new sales personnel in India, South Korea and the UK
- Evolution of product suite to meet identified market opportunities: LiverSmart<sup>™</sup> a new AI medical device, which combines two existing regulatory-cleared Resonance Health products (FerriSmart<sup>®</sup> and HepaFat-AI<sup>®</sup>) into a single multi-parametric MRI session, undergoing final quality and verification checks prior to its submission for regulatory approval in the US
- Antisense Oligonucleotide RNA Therapeutics R&D Project limited dosing study in humanised-liver mouse model completed, with treatment well-tolerated by the humanised-liver mouse while suppressing disease markers of liver inflammation and fibrosis
- Underlying demand for the Company's products and services remains robust with sales volumes exceeding both 2020 and 2019 on a calendar year-to-date basis

Resonance Health Ltd (ASX: RHT) (**Resonance Health** or **Company**) is pleased to release its Appendix 4C – Quarterly Activities & Cashflow Report for the quarter ended 30 September 2021.

# **Building for Growth**

Resonance Health is focused on building its business strategy and capability to drive future growth, on the foundations of its established product suite, excellent technical reputation, solid market position, and revenue base.

This focus has involved three key areas of activity for the Company during the quarter – developing and commencing execution of a global sales and marketing strategy; recruiting a high-calibre sales and marketing and technology team; and further product development aligned to identified market opportunities.

# **Global Sales & Marketing Strategy**

There is a recognised and growing clinical need worldwide for products and services to assist in the identification and management of blood disorder-related iron overload diseases and organ fat diseases. It is critical that these services be accurate, standardised, cost-effective, capable of rapid turnaround, and as non-invasive for the patient as possible.

The Company's existing regulatory-approved product suite - encompassing FerriScan<sup>®</sup>, FerriSmart<sup>®</sup>, HepaFat-Scan<sup>®</sup>, HepaFat-AI<sup>®</sup>, and Cardiac T2<sup>\*</sup> - directly fulfil these needs and achieve these high standards of delivery. These products are also being further developed and enhanced to closely match market opportunities that have been identified.

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# Haemoglobin disorders

Approximately 5-7% of the world population is a carrier of a severe blood disorder which includes people with hemochromatosis, sickle cell disease, and thalassaemia<sup>1</sup>. It is estimated that between 300,000 and 500,000 children are born each year with a severe haemoglobin disorder<sup>2</sup>. Management of these disorders requires lifelong treatment. The side-effects of this treatment and the disorder itself can give rise to excess toxic iron levels in the liver and other organs, which if unmonitored and untreated can lead to serious organ damage and failure.

There is a genetic pre-disposition to haemoglobin disorders in tropical and subtropical regions, with these disorders occurring most frequently in people with African, southern Asian, Middle Eastern and southern European ancestry.

# Fatty liver disease

Non-Alcoholic Fatty Liver Disease (**NAFLD**) is an emerging category of serious disease that is closely associated with the rise of obesity, diabetes and metabolic syndrome. Studies have also shown that people with NAFLD are at increased risk of cirrhosis and cancer<sup>3</sup>.

NAFLD is estimated to affect 24-30% of the global population, equating to 1.8-2.3 billion people. While NAFLD is increasingly prevalent in affluent Western economies, its global prevalence is widespread and encompasses the Middle East (32%), South America (31%), Asia (27%), the United States (24%), Europe (23%) and Africa  $(14\%)^4$ .

In the US there is an estimated 80 to 90 million people affected by NAFLD, with an associated cost to the US healthcare system estimated to be US\$32 billion<sup>5</sup>.

# Sales & marketing strategy

Resonance Health's sales and marketing strategy is targeting key markets that are defined by disease prevalence and aptitude for AI/software-based diagnosis. In addition to targeting new customers in these markets, our strategy involves connecting with our large base of global FerriScan<sup>®</sup> and HepaFat-Scan<sup>®</sup> customers and building the foundation for distribution of our current and future artificial intelligence (AI) portfolio (FerriSmart<sup>®</sup>, HepaFat-AI<sup>®</sup>, and LiverSmart<sup>™</sup>).

The Company's marketing strategy includes developing a clinical and treatment-based approach to positioning our products, working with Key Opinion Leaders (KOLs) globally to promote our products via research publications, as well as attendance at global conferences. Resonance Health is also seeking to broaden its pharma partnerships, where Resonance Health works with various pharmaceutical companies to utilize our products as companion diagnostics in current and upcoming clinical trials.

Resonance Health is also actively engaging with international disease awareness advocates like the Thalassaemia International Federation (**TIF**) and physicians in emerging countries to help patients suffering from chronic iron dysfunction disorders get access to better care and earlier diagnosis.



# **Recruiting for Growth**

# Global sales & marketing team

Resonance Health is prioritising the establishment of a dedicated, high-calibre global sales and marketing team to drive market awareness, customer engagement and sales growth.

This commenced with the key appointment of Mr Ajay Nair to the new role of General Manager - Global Sales & Marketing (ASX Announcement 7 July 2021) which has now been followed by the hiring of a Global Marketing Manager based at the Company's head office in Australia.

Resonance Health has now completed the recruitment of key roles in the Company's established markets of the US and UK, including a US-based Sales Manager, a US-based Clinical Trials Specialist, and a UK-based sales representative. In addition, new sales representative appointments have been made in identified growth markets in India and South Korea.

#### Technology development team

Resonance Health is building a highly capable technology development team, commencing with the recent recruitment of a Chief Technology Officer (**CTO**) and a Senior Software Developer. The Technology team will drive ongoing product development and enhancements and improved integration with customer systems, and improvements in service delivery and customer experience.

# **Product Evolution & Development**

### New AI medical device - LiverSmart™

The Company announced the development of a new Al medical device, LiverSmart<sup>™</sup>, which is now undergoing final quality and verification checks prior to its submission for regulatory clearances.



LiverSmart<sup>™</sup> combines two existing regulatory-cleared Resonance Health AI products, FerriSmart<sup>®</sup> and HepaFat-AI<sup>®</sup>, into a single multi-parametric MRI session, avoiding the need for multiple MRI appointments, and delivering a more complete and comprehensive assessment of a person's liver.

Clinicians seeking both analyses will simply refer for a LiverSmart<sup>™</sup> assessment, by Resonance Health. LiverSmart's use remains subject to regulatory clearances including US Federal Drug Administration (**FDA**) regulatory clearance. LiverSmart<sup>™</sup> is currently undergoing final quality and verification checks and the Company anticipates being in a position to submit LiverSmart's application for FDA clearance within the coming weeks.

#### LiverSmart<sup>™</sup> CPT Code Eligibility

Importantly, the Company believes that LiverSmart<sup>™</sup> may be eligible for two new United States (Category III) Current Procedural Technology (**CPT**) codes recently published by the American Medical Association (**AMA**) and which become active on 1 January 2022. The Company is awaiting definitive determination of LiverSmart's eligibility for these codes, from a US certified CPT coder.

CPT codes are recognized by US government agencies are used by physicians and health care professionals for systematically reporting and tracking medical services performed by healthcare providers. If the codes are confirmed as applicable to LiverSmart<sup>™</sup> it will facilitate the Company seeking reimbursement for LiverSmart<sup>™</sup> by private payers such as private health insurers, as well as Medicare and Medicaid.



#### Antisense Oligonucleotide RNA Therapeutics Project

Resonance Health has further progressed its Antisense Oligonucleotide (**ASON**) RNA Therapeutics Project with the completion of a limited dosing study in humanised-liver mouse model. The treatment was found to suppress disease markers of liver inflammation and fibrosis while also being well-tolerated by the humanised-liver mouse subjects.

The data validates the Company's ASON treatment strategy for chronic HBV, consolidates the intellectual property position, and supports continued investigation of AS3 in a preclinical animal model of disease. Subject to further studies, the Company aims to investigate if AS3 is effective in an HBV infection model using the same strain. Successful elimination of HBV will require a multi-drug approach, and because AS3 targets a human protein essential for viral growth, it is ideally suited to this purpose.

### **Financial & Operating Performance**

Underlying demand for the Company's products and services remains robust with sales volumes exceeding both 2020 and 2019 pre-COVID levels. On a calendar year-to-date basis, chargeable analysis service volumes up to the end of September 2021 were 18% higher than the corresponding period in 2020 and 5% higher than 2019.

Expenditure during the quarter included a total of \$278K in capitalised and non-capitalised R&D expenditure in relation to the Company's identified R&D priorities, including the LiverSmart<sup>™</sup> project. In addition, quarterly cashflows reflected one-off costs for staff changes and a change of office premises totalling approximately \$120K.

With respect to item 6 of the Appendix 4C cash flow report for the quarter, payments to related parties of approximately \$133K were made during the quarter. This comprised of \$35K of remuneration paid to non-executive directors, \$65K of remuneration paid to Mr Mitchell Wells as Managing Director, and \$33K for consultancy services provided by Mr Wells prior to his appointment as Managing Director for consulting services performed in the previous quarter.

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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 technology and services company, specialising in the development and delivery of non-invasive medical imaging software and services.

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 has gained



endorsement by leading physicians worldwide for consistently providing high quality quantitative measurements essential in the management of diseases.

Resonance Health's dedication to scientific rigour and quality management has enabled it to achieve regulatory clearances for a range of Software as a Medical Device (**SaMD**) products in the USA, Europe, and Australia and to proudly carry ISO 13485 certification for the design and manufacture of medical devices. A number of these SaMD products incorporate the use of Artificial Intelligence (**AI**):

- FerriScan<sup>®</sup> provides an accurate measurement of liver iron concentration (LIC) through a non-invasive MRI-based technology, for use in the assessment of individuals with iron overload conditions. FerriScan is internationally recognised as the gold standard in LIC assessment
- FerriSmart<sup>®</sup> an Al-driven system for the automated real-time measurement of LIC in patients using non-invasive MRI-based technology
- HepaFat-Scan<sup>®</sup> an MRI-based solution which provides a reliable non-invasive measure of liver fat in liver tissue for use in the assessment of individuals with confirmed or suspected fatty liver disease
- HepaFat-AI<sup>®</sup> an AI-driven system for the automated real-time multi-metric measurement of liver fat in patients using non-invasive MRI-based technology

The Company has an active development pipeline of additional medical imaging analysis products and services, including **LiverSmart™**, which combines FerriSmart<sup>®</sup> and HepaFat-AI<sup>®</sup> into a single multi-parametric MRI session, avoiding the need for multiple MRI appointments and delivering a more complete and comprehensive assessment of a person's liver.

<sup>&</sup>lt;sup>1</sup> Thalassaemia International Federation, 2021

<sup>&</sup>lt;sup>2</sup> Thalassaemia International Federation, 2021

<sup>&</sup>lt;sup>3</sup> "Effect of Metabolic Traits on the Risk of Cirrhosis and Hepatocellular Cancer in Nonalcoholic Fatty Liver Disease", *Hepatology*, March 2020

<sup>&</sup>lt;sup>4</sup> "Non-alcoholic Fatty Liver Disease and Alcohol-Related Liver Disease: Two Intertwined Entities", *Frontiers in Medicine*, 20 August 2020

<sup>&</sup>lt;sup>5</sup> "Economic burden of fatty liver disease in US is \$32 billion annually", *Intermountain Medical Center of Salt Lake City*, 3 July 2018

# Appendix 4C

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

### Name of entity

**Resonance Health Limited** 

# ABN

96 006 762 492

Quarter ended ("current quarter")

30 September 2021

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000	
1. Cash flows from operating activities				
1.1	Receipts from customers	708	708	
1.2	Payments for			
	(a) research and development	(139)	(139)	
	<ul> <li>(b) product manufacturing and operating costs</li> </ul>			
	(c) advertising and marketing	(105)	(105)	
	(d) leased assets			
	(e) staff costs	(566)	(566)	
	(f) administration and corporate costs	(235)	(235)	
1.3	Dividends received (see note 3)			
1.4	Interest received	3	3	
1.5	Interest and other costs of finance paid			
1.6	Income taxes paid			
1.7	Government grants and tax incentives			
1.8	Other (provide details if material)			
1.9	Net cash from / (used in) operating activities	(334)	(334)	

2.	Cash flows from investing activities		
2.1	Payments to acquire or for:		
	(a) entities		
	(b) businesses		
	(c) property, plant and equipment	(50)	(50)
	(d) investments		
	(e) intellectual property	(139)	(139)
	(f) other non-current assets		

ASX Listing Rules Appendix 4C (17/07/20) + See chapter 19 of the ASX Listing Rules for defined terms.

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 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	(189)	(189)

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		
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 (security deposit)	(37)	(37)
3.10	Net cash from / (used in) financing activities	(37)	(37)

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	8,857	8,857
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(334)	(334)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(189)	(189)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000	
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(37)	(37)	
4.5	Effect of movement in exchange rates on cash held	91	91	
4.6	Cash and cash equivalents at end of period	8,388	8,388	

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	7,367	2,669
5.2	Call deposits	1,021	6,089
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)	8,388	8,857

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	133
6.2	Aggregate amount of payments to related parties and their associates included in item 2	
	if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must includ nation for, such payments.	le a description of, and an

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
7.1	Loan facilities		
7.2	Credit standby arrangements		
7.3	Other (please specify)		
7.4	Total financing facilities		
7.5	Unused financing facilities available at qu	larter end	
7.6	Include in the box below a description of eac rate, maturity date and whether it is secured facilities have been entered into or are propo include a note providing details of those facil	or unsecured. If any add osed to be entered into af	itional financing

8.	Estim	nated cash available for future operating activities	\$A'000
8.1	Net ca	ish from / (used in) operating activities (item 1.9)	(334)
8.2	Cash a	and cash equivalents at quarter end (item 4.6)	8,388
8.3	Unuse	ed finance facilities available at quarter end (item 7.5)	
8.4	Total a	available funding (item 8.2 + item 8.3)	8,388
8.5	Estim item 8	ated quarters of funding available (item 8.4 divided by 8.1)	25.11
		the entity has reported positive net operating cash flows in item 1.9, answer iter or the estimated quarters of funding available must be included in item 8.5.	n 8.5 as "N/A". Otherwise, a
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?		
	Answe	er: N/A	
	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?		
	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	ve 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.

Date: 29 October 2021

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

#### 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.