ASX Announcement – 21 December 2022

RESONANCE HEALTH LODGES MRI FIBROSIS PROVISIONAL PATENT APPLICATION

Highlights

- Provisional patent application lodged in relation to an invention for the detection and assessment of fibrosis in the liver and potentially other organs
- Application based on initial proof of concept results, utilising a novel approach devised and developed by a team lead by Resonance Health's Chief Scientific Officer, Dr. Wenjie Pang
- Initial proof of concept shows strong predictive capability to identify the presence of liver fibrosis, utilising standard MRI equipment and acquisition sequences
- Liver disease is a leading cause of mortality worldwide. Early identification of liver fibrosis (or scarring) is essential to managing and reversing the progress of liver disease
- Current gold standard for identifying and assessing liver fibrosis is liver biopsy; other non-invasive methods are potentially subject to significant confounding factors and other unresolved issues in relation to the accurate and reliable detection of fibrosis using these methods
- Resonance Health is now undertaking an accelerated (6 to 12 month) extended proof of concept liver fibrosis study on an expanded population
- Subject to the results of the extended proof of concept, Resonance Health intends to engage with industry pharmas and clinical key opinion leaders who have indicated strong interest in exploring collaboration opportunities

Resonance Health Ltd (ASX:RHT) (**Resonance Health** or **Company**) is pleased to advise that it has lodged a provisional patent application in relation to an invention for the detection and assessment of fibrosis in the liver and other organs, utilising non-invasive magnetic resonance imaging (**MRI**).

Liver Disease & Fibrosis

Liver Disease

Liver disease is a leading cause of mortality worldwide and incorporates a wide range of diseases. Most notably, these diseases include non-alcoholic fatty liver disease (**NAFLD**) and non-alcoholic steatohepatitis (**NASH**); the most common liver diseases worldwide affecting an estimated one-quarter of the world's population[1].

In addition, viral hepatitis is incurable and imparts a high disease burden throughout the world, with 257 million and 71 million individuals living with hepatitis B virus (**HBV**) and hepatitis C virus (**HCV**) infection respectively.[2,3]

Liver Fibrosis

Liver cirrhosis (an advanced form of liver fibrosis or scarring) caused by these diseases is a one of the main causes of death worldwide and one of the leading causes of disability-adjusted life years.[4]

Liver fibrosis is largely reversible if detected early in its progression. However, once liver fibrosis progresses to cirrhosis, it typically gives rise to greatly diminished liver function with major associated negative health impacts and, ultimately, organ failure that requires a liver transplant as the only available treatment.

Detection & Assessment of Liver Fibrosis

Early detection and assessment of liver fibrosis is essential to managing and reversing liver disease progression. The current gold-standard for assessing the presence and progression of liver fibrosis is by way of liver biopsy, which involves the collection of a tissue sample from the patient using a needle, which is then analysed by a pathologist.

Liver biopsies are not trivial procedures; they are invasive, can give rise to significant side effects (including pain, bleeding, infection, hospitalisation, and even death) and are unavailable for patients with comorbidity factors including blood clotting conditions and infections. Further, liver biopsies are slow and expensive as they require the involvement of multiple medical specialists and facilities, and they may be subject to significant sampling error.

Current Non-Invasive Approaches to Liver Fibrosis

Several techniques exist that purport to indicate the presence of liver fibrosis utilising non-invasive or less-invasive procedures than liver biopsy. These include serum blood tests, ultrasound, and magnetic resonance elastography (**MRE**) methods and quantitative MRI methods.

While these non-invasive methods may provide information as to the presence of liver fibrosis (particularly advanced fibrosis), there are a number of unresolved issues in relation to the accurate and reliable detection of fibrosis using these methods. In addition, the techniques are typically confounded by the presence of factors including liver iron level (or content), subcutaneous fat, ascites, liver fat, liver inflammation and others.

Successful Initial Proof of Concept Study

Resonance Health has completed an initial proof-of-concept study of an analysis technique aimed at the identification and assessment of liver fibrosis (**Initial Proof of Concept**). The Initial Proof of Concept forms the basis of the invention that is the subject of the Provisional Patent Application.

The Initial Proof of Concept study, which was conducted on a patient and control group of 30 subjects, indicates a strong capability to predict the absolute presence of liver fibrosis within the study population.

Next Steps – Extended Proof of Concept

Based on the extremely promising Initial Proof of Concept results Resonance Health is now undertaking an accelerated extended proof-of-concept study with an expanded study population (**Extended Proof of Concept**).

Extended Proof of Concept

The objectives of the Extended Proof of Concept are to confirm the results of the Initial Proof of Concept, to further refine the study predictive models and to further assess the performance of predictive models and their capacity to distinguish between differing fibrosis grades.

The duration of the Extended Proof of Concept is estimated to be 6 to 12 months. The Company is actively engaged with study partners to secure the study subjects required for the study and will update shareholders once the timelines for completion of this phase of the study are determined.

Collaboration Opportunities

Subject to the outcomes of the Extended Proof of Concept, the Company intends to explore collaboration opportunities with large pharmaceutical companies and clinical key opinion leaders (**KOLs**), who have expressed strong interest in the results of the Initial Proof of Concept and a desire to participate in such a collaboration.

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

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About Resonance Health

Resonance Health is an Australian healthcare technology and services company. The Company's services are used globally by clinicians in the management of human diseases and by pharmaceutical and therapeutic companies in their clinical trials. Resonance Health has gained endorsement by leading physicians worldwide for providing high quality quantitative assessments essential in managing diseases and drug development.

Resonance Health's dedication to scientific rigour and quality has enabled it to achieve regulatory clearances for a range of Software-as-Medical Devices (**SaMDs**) in the USA, Europe, UK, and Australia, and to proudly carry ISO 13485 certification for the design and manufacture of medical devices. Regulatory cleared SaMD products, some of which incorporate Artificial Intelligence (**AI**), include:

- **FerriScan®,** a core-lab product that provides an accurate assessment of liver iron concentration (**LIC**) through non-invasive MRI-based technology, for use in the assessment of individuals with iron overload conditions. Internationally recognised as the gold standard in LIC assessment.
- **FerriSmart®,** an AI-assisted, non-invasive MRI-based device for the automated real-time assessment of LIC in patients, calibrated against the global gold standard, FerriScan®.
- **HepaFat-Scan®,** an MRI-based solution which provides a reliable, non-invasive assessment of liver-fat in liver tissue for use in the assessment of individuals with confirmed or suspected fatty-liver-disease.
- **HepaFat-AI®,** an AI-assisted, non-invasive device for the automated real-time multi-metric assessment of liver-fat in patients, for the assessment of individuals with confirmed or suspected fatty liver disease.
- **LiverSmart®,** an AI-assisted, non-invasive MRI-based multi-parametric device combining FerriSmart® and HepaFat-AI® into a consolidated report providing accurate assessment of LIC and liver fat.
- **CardiacT2*,** the most widely accepted MRI method for assessing heart iron loading. Resonance Health offers a dual analysis of FerriScan® and CardiacT2*. CardiacT2* is TGA and CE Marking regulatory cleared.

The Company has a development pipeline of additional medical imaging analysis products and services, including **CardiacT2*-AI** an AI tool for the automated analysis and quantification of cardiac-iron levels and **LungSmart (Alert-PE™)**, an AI tool for the automated review of chest CT scans of patients with suspected PE.

Stakeholders, including clinicians, patients, and shareholders, are encouraged to register their interest at www.resonancehealth.com and to follow Resonance Health on Facebook, LinkedIn, and Twitter.

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[2] Blach S, Zeuzem S, Manns M, Altraif I, Duberg A, Muljono DH, et al. (2017) Global prevalence and genotype distribution of hepatitis C virus infection in 2015: a modelling study. Lancet Gastroenterol Hepatol. 2(3):161–176. https://doi.org/10.1016/S2468-1253(16)30181-9 PMID: 28404132

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