
Resonance Health Contracted for Third Party NASH Phase II Clinical Trial

Highlights

- Resonance Health contracted by VGI Health Technology Ltd for NASH Phase II clinical study
- HepaFat-AI® to be used for the first time in a third-party NASH clinical study environment
- Liver-fat of 100 subjects to be assessed using HepaFat-AI® at 2-3 timepoints over 18 months
- VGI Health Technology Ltd (NSX: VTL) develops nutraceuticals and pharmaceuticals based on two proprietary and patented platforms

Resonance Health Contracted for NASH Clinical Trial

Resonance Health Ltd (ASX: RHT) (“Resonance Health” or the “Company”) advises that it has been contracted to provide liver-fat quantification services for Invictus Ops Pty Ltd, a wholly owned subsidiary of NSX-listed VGI Health Technology Ltd (NSX: VTL) (“VGI Health Technology”), for its clinical study (“Study”) on a potential new treatment for Non-Alcoholic Steatohepatitis (“NASH”).

Study and Contract Details

The Company’s involvement in the Study is expected to span 18 months and involve approximately 100 trial participants. Resonance Health’s recently (December 2020) regulatory-cleared HepaFat-AI® medical device will be used for the first time in a clinical study environment to measure, grade, and quantify the liver fat of the trial participants at two-three timepoints over the 18-month period.

This is the first time HepaFat-AI® will be used in a third-party NASH clinical trial, which validates the efficacy of the device in a clinical trial context and establishes a precedent for other clinical trial procurement efforts in the prolific and growing fatty-liver space. The contract value is estimated to be approximately A\$100K although VGI Health Technology may discontinue or extend the Study at any time in which case the Company will be paid for services performed up to the termination date.

Fatty Liver Disease – An Emerging Global Health Crisis

Fatty liver disease is emerging as a major global health issue and is attracting significant attention from international pharmaceutical companies seeking to develop effective drug treatments for the disease.

It is estimated that 24-30% of the global population suffers from Non-Alcoholic Fatty Liver Disease (“NAFLD”) which roughly equates to 1.8-2.3 billion people. Of these, it is estimated that 20%, or 0.5 billion people, will also develop NASH, a severe form of NAFLD which can cause liver damage including fibrosis and cirrhosis and which often requires immediate medical intervention.¹

If the prevalence of NAFLD continues to rise in line with the global obesity epidemic, it is predicted that the healthcare burden of NAFLD over the next 10 years could increase to \$1.005 trillion in the USA alone.²

Managing Director of Resonance Health, Mr. Mitchell Wells commented:

“We are delighted to assist Invictus with its NASH Phase II clinical study through the provision of HepaFat-AI® and we applaud Invictus for their efforts to find treatments for NASH. Fatty liver diseases are on the rise and Resonance Health can help combat this global epidemic with its products and services that quantify and measure fat in the liver, including HepaFat-AI®, HepaFat-Scan® and LiverSmart®. The study is a material achievement in that this is the first time HepaFat-AI® will be used in a NASH clinical trial, and it sets an important precedent.”

CEO and Managing Director of VGI Health Technology, Dr. Glenn Tong commented:

“NASH is an unmet need which has presented great challenges to many drug development groups. Our NASH drug candidate, IVB001, targets multiple parts of the disease pathway including the steatosis (the accumulation of fat in the liver) which causes oxidative stress which in turn causes inflammation which results in fibrosis (the production of collagen and scarring of the liver). The partnership with Resonance Health will vastly improve the efficiency with which we measure key endpoints for this clinical study which is due to commence recruitment of patients shortly.”

About HepaFat-AI®

HepaFat-AI® assesses the volumetric liver fat fraction (“VLFF”), proton density fat fraction (“PDFF”), and steatosis grade in individuals with fatty liver disease. It can be used by clinicians to monitor liver fat content in patients or clinical study participants.



HepaFat-AI® assesses the volumetric liver fat fraction (“VLFF”), proton density fat fraction (“PDFF”), and steatosis grade in individuals with confirmed or suspected fatty liver disease. It can be used by clinicians to monitor liver fat content in patients or clinical study participants.

HepaFat-AI® automatically analyses magnetic resonance imaging (“MRI”) datasets to assess liver fat, providing a comprehensive multi-metric tool for use in the assessment of fatty liver. HepaFat-AI® produces a patient report for clinical interpretation, which includes a fat map illustrating the distribution of fat in the liver.

HepaFat-AI® gained US Food & Drug Administration (“FDA”) regulatory clearance in December 2020, and European (EU) CE Mark and Australian TGA clearances soon thereafter.

About VGI Health Technology

VGI Health Technology is an NSX-listed Australian public company based in Sydney, NSW (NSX: VTL). VGI Health Technology is an early-stage health and clinical phase biopharma company involved in the development, production, marketing and sale of health and wellbeing products, including the development and commercialization of platforms for the non-invasive delivery of tocotrienols (a form of Vitamin E) for both nutraceutical and pharmaceutical applications.

A nutraceutical product is a substance that has physiological benefits or provides protection against chronic disease. The term “nutraceutical” is used to describe medicinally or nutritionally functional foods or food supplements. Pharmaceuticals are a product of scientific research that supports their claims for health improvement. VGI Health Technology is focused on (i) the marketing and sale of nutraceutical and wellbeing products with the objective of delivering near term revenues; and (ii) the development of prescription medicine candidates for NAFLD and pancreatic cancer.

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

For further information please contact:

Mitchell Wells

Managing Director, Resonance Health Ltd

E: mitchellw@resonancehealth.com

P: +61 (0)8 9286 5300

About Resonance Health

Resonance Health is an Australian healthcare technology and services company, specialising in the development and delivery of noninvasive 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 diagnosis and 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. Some of the SaMD products incorporate the use of Artificial Intelligence (**AI**):

- **FerriSmart**[®] - an AI-driven non-invasive MRI-based device for the automated real-time measurement of liver iron concentration in patients.
- **HepaFat-AI**[®] - an AI-driven non-invasive MRI-based device for the automated real-time multi-metric measurement of liver fat in patients, for use in the assessment of individuals with confirmed or suspected fatty liver disease.
- **LiverSmart**[®] - an AI-driven non-invasive MRI-based multi-parametric device that combines FerriSmart[®] and HepaFat-AI[®] into a consolidated report that provides accurate measurement of liver iron concentration and liver fat.
- **FerriScan**[®] - a core-lab product that provides accurate measurement of liver iron concentration 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.
- **CardiacT2*** – the most widely accepted MRI-based method for assessing heart iron loading. Resonance Health offers a dual analysis of FerriScan[®] and CardiacT2*. CardiacT2* has regulatory clearance from the TGA and CE Mark.

The Company has an active development pipeline of additional medical imaging analysis products and services, including, **LungSmart**[®] and **Alert-PE**[™], AI tools for the automated review of chest CT scans of patients with cystic fibrosis and suspected pulmonary embolism, respectively.

Stakeholders including clinicians and patients are encouraged to follow Resonance Health on FaceBook, LinkedIn and Twitter.



- ¹ 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
- ² Younossi, Z. M. et al. The economic and clinical burden of nonalcoholic fatty liver disease in the United States and Europe. *Hepatology* 64, 1577–1586 (2016). Younossi, Z.M. (2018), The epidemiology of nonalcoholic steatohepatitis. *Clinical Liver Disease*, 11: 92-94. doi:10.1002/cld.710