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VGI Health Technology Limited contracts Resonance Health Ltd for NASH Phase II clinical study

Highlights

- VGI Health's wholly owned subsidiary Invictus Ops Pty Ltd has contracted Resonance Health for its NASH Phase II clinical study
- Resonance Health's HepaFat-AI® to be used for the first time in a third-party NASH clinical study environment
- Liver-fat of 100 participants to be assessed by HepaFat-AI® at 2-3 timepoints over 18 months

Sydney New South Wales, 25 January 2022 – Invictus Ops Pty Ltd ("Invictus"), a wholly owned subsidiary of NSX-listed VGI Health Technology Limited (NSX: VTL), is pleased to announce that it has contracted Resonance Health Ltd (ASX: RHT) ("Resonance Health") to provide liver-fat quantification services for its clinical study ("Study") on a potential new treatment for Non-Alcoholic Steatohepatitis ("NASH").

This Study is expected to span 18 months and involve approximately 100 trial participants. Resonance Health's recently (December 2020) US FDA regulatory cleared HepaFat-AI® medical device will be used for the first time in a NASH 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 and is therefore a milestone in the commercialisation of this technology platform. Importantly, the use of HepaFat-AI® in the Study further validates the efficacy of the device and sets a precedent for other clinical trial procurement efforts by Resonance Health. The contract value is estimated to be approximately A$100K and VGI Health Technology may discontinue or extend the Study at any time in which case the Resonance Health will be paid for services performed up to the termination date or additional payments may be due for any extension of the Study.

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.[i]

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.[ii]

The 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."

The CEO and Managing Director of VGI Health Technology Limited and Director of Invictus Ops Pty Ltd., 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."

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About VGI Health Technology Limited

VGI Health Technology Limited trading as VGI Health Technology is an Australian public listed biotechnology company (NSX:VTL) developing and commercialising novel dietary supplements and prescription medicines based on natural products (tocotrienols) which have wide therapeutic potential, including: Delayed Onset Muscle Soreness, muscle recovery, exercise endurance, Non-Alcoholic Fatty Liver Disease (NAFLD), Non-Alcoholic SteatoHepatitis (NASH), pancreatic cancer, hyperlipidaemia, hypertension and diabetes. VTL owns and controls patent and other intellectual property rights for novel approaches to non-invasively delivering tocotrienols directly to the target tissues. The Companyhas a product development program for evidence-based nutraceuticals and a clinical development program for prescription medicines.

For more information see: https://www.vgiht.com

Investors interested in trading shares on the NSX should contact a broker who is an NSX Participant:https://www.nsx.com.au/broker_list_print.asp

About HepaFat-AI®

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.

It is estimated that 24-30% of the global population has Non-Alcoholic Fatty Liver Disease ("NAFLD") which roughly equates to 1.8-2.3 billion people[iii]. Of these, it is estimated that 20%, or 468 million people, will also develop NASH, a severe form of NAFLD which can cause liver damage including fibrosis and cirrhosis, which often requires immediate medical intervention. 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[iv].

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 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 system for the automated real-time measurement of Liver Iron Concentration in patients using non-invasive MRI-based technology.

- **HepaFat-AI® -** an AI-driven system for the automated real-time multi-metric measurement of liver fat in patients using non-invasive MRI-based technology, for use in the assessment of individuals with confirmed or suspected fatty liver disease.

- **LiverSmart®** - Combining FerriSmart and HepaFat-AI in one integrated solution that provides accurate measurement of liver iron concentration and liver fat through a multi-parametric non-invasive MRI-based technology.

- **FerriScan®** - a core-lab product provides accurate measurement of liver iron concentration through 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.

- **CardiacT2* –** the most widely accepted MRI based method for assessing heart iron loading. Resonance Health also offers a dual analysis of FerriScan® and CardiacT2*. CardiacT2* has regulatory clearance from the FDA, 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

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[i] 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

[ii] 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

[iii] 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

[iv] 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