Resonance Health Ltd
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FDA Clearance for HepaFat-Scan®

Resonance Health is pleased to announce that it has received from the U.S. Food and Drug Administration (FDA) 510(k) market clearance for the HepaFat-Scan® medical device. HepaFat-Scan® is a software technology that can be used to accurately measure the amount of fat in the liver, using MRI medical images.

This is a significant milestone for the Company. Gaining FDA approval enables Resonance Health to commercially market the test in the United States, providing patients and clinicians with an offering that provides key differences to other diagnostic tests for fatty liver.

Over two-thirds of the general population of the United States is either overweight or obese. Obesity and the metabolic syndrome are the most common risk factors for the development of non-alcoholic fatty liver disease (NAFLD). It is estimated that about 30% of the U.S. population has NAFLD and data from adult transplant centers suggest that liver transplantation due to fatty liver related disorders is increasing dramatically.

Clinical screening for fatty liver is a significant challenge. Liver biopsy remains the gold standard for making the definitive diagnosis of fatty liver disease but it is not well suited for screening or monitoring because of its invasive nature, cost, and complications. As such, health care providers need alternative tools to help make the diagnosis in adults and children. Utilising MRI images, HepaFat-Scan® is a safe non-invasive diagnostic tool.

HepaFat-Scan® provides considerably improvements over other diagnostic tools for fatty liver disease. The superior sensitivity of HepaFat-Scan® will provide patients and doctors with a more accurate diagnostic tool as part of a structured intervention protocol or clinical research trial. HepaFat-Scan® will be attractive not only to patient and health care professions but also to the pharmaceutical industry developing new therapies to address fatty liver disease.

In obtaining FDA approval, Resonance Health demonstrated the accuracy and reproducibility of HepaFat-Scan® through a combination of bench testing and clinical studies. This approval is an excellent result for the Company and the culmination of a great deal of hard work from the Resonance Health team, which can now move forward with the commercialization strategy for HepaFat-Scan®.

By Order of the Board, Resonance Health Limited

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