resonance health limited



The Manager

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Company Announcements Australian Stock Exchange 4<sup>th</sup> Floor 20 Bridge Street SYDNEY NSW 2000

Dear Sir,

## FDA approves FerriScan<sup>™</sup> non-invasive test for iron overload disease

**Perth, Australia, Friday 28 January 2005:** Resonance Health Limited (ASX:RHT) announced today that its subsidiary, Inner Vision Biometrics Pty Ltd (IVB), has achieved U.S. Food and Drug Administration (FDA) marketing approval for FerriScan<sup>™</sup> its novel non-invasive diagnostic test for liver iron concentration.

FDA 510(k) approval allows IVB to market the FerriScan<sup>™</sup> test in the United States where an estimated four million people are afflicted with an iron overload disease such as haemochromotosis and thalassaemia.

FDA 510(k) approval for FerriScan<sup>™</sup> follows the listing of FerriScan<sup>™</sup> by the Australian regulatory authority, the Therapeutic Goods Administration (TGA), and European CE Mark approval achieved at the end of 2004. FerriScan<sup>™</sup> can now be marketed in the two largest international markets, the USA and Europe. Existing partnerships with leading diagnostic imaging companies will be used to offer the FerriScan<sup>™</sup> test to the public in Australia and Europe. Partnerships with diagnostic imaging companies are also being developed for the USA.

"We are delighted to have received such rapid FDA approval for FerriScan<sup>™</sup> which provides us with access to the world's largest market for the test. We will be meeting with major U.S. based diagnostic imaging groups over the next several weeks to accelerate arrangements for the U.S. commercial launch of the FerriScan<sup>™</sup> test. The U.S. has a well developed MRI infrastructure and attractive pricing to underpin commercial success for FerriScan<sup>™</sup>," said Mr. Tony Fitzgerald, Executive Director of Resonance Health.

"U.S. FDA marketing approval, the achievement of European CE Mark and listing on the ARTG by the TGA in Australia will enable access to the major international markets for the FerriScan<sup>™</sup> test. We plan to partner with leading diagnostic imaging companies in the US, Europe and Australia to offer the FerriScan<sup>™</sup> test to the public."

## Further information

## About Haemochromotosis and Thalassaemia

Haemochromotosis is a genetic disorder that causes iron deposition in the liver, and in other organs of the body, resulting in iron overload. The condition frequently remains undiagnosed because of lack of awareness, its long latency period and its non-specific symptoms.

Thalassaemia, a genetic blood disorder and a very severe and debilitating form of anaemia, also results in iron overload due to the requirement for frequent blood transfusions.

## About Resonance Health Ltd

Resonance Health Limited controls 51% of the voting rights of Inner Vision Biometrics Pty Ltd (IVB) and is earning 51% of the equity of IVB via the progressive injection of further capital. FerriScan<sup>™</sup> is 100% owned by IVB.

FerriScan<sup>™</sup> is a novel, non-invasive diagnostic test of the iron content of a patient's liver to assist clinicians in the detection and treatment of iron overload disorders such as thalassemia and hereditary haemochromatosis. The FerriScan<sup>™</sup> diagnostic test service uses existing MRI (magnetic-resonance imaging) machines at radiology facilities worldwide which can be configured to provide a suitable scan of the liver that is subsequently analysed at the centralised IVB image analysis centre to quantify iron loading using proprietary software. The FerriScan<sup>™</sup> test provides a safe alternative to liver biopsy and will become a valuable adjunct to gene testing for iron overload diseases. Liver biopsy is an unpleasant, invasive procedure requiring liver tissue to be extracted from the patient by needle.

Further information concerning Resonance Health and FerriScan<sup>™</sup> can be obtained from the following web sites: <u>www.resonancehealth.com</u> <u>www.ferriscan.com</u>

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