
LIVER FIBROSIS RESULTS OPEN UP GLP-1 BIOMARKER OPPORTUNITY

Highlights

- **FibrosisAssessment** aims to measure fibrosis in the liver using MRI sequences without expensive hardware or invasive contrast injections
 - **Fibrosis in the liver** is a key biomarker endpoint in GLP-1, metabolic disease, and obesity clinical trials
 - Preliminary results from the extended proof-of-concept (EPoC) in non-invasive MRI liver fibrosis, against liver biopsy, show that **FibrosisAssessment** accuracy (AUROC) is in line with the widely used FibroScan ultrasound device (US\$150K) for significant fibrosis.
 - **Significant fibrosis Results ($\geq F2$)** - AUROC 0.82 (95% CI 0.67–0.94) | specificity 80%, sensitivity 75.0%
 - **Advanced fibrosis Results ($\geq F3$)** - AUROC 0.79 (95% CI 0.63–0.91) | specificity 93.5%, sensitivity 57.9%
 - **FibrosisAssessment** device complements existing **TrialsWest** business where Resonance is running multiple GLP-1 and metabolic disease trials
 - **US\$1.3 billion market opportunity** to sell **FibrosisAssessment** into pharma trials
 - **Builds on 20 years** of developing and commercialising 'Software as a Medical Device' (SaMD)
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Preliminary EPoC Results for Resonance's Non-Invasive MRI Liver Fibrosis Device (FibrosisAssessment)

Resonance Health Ltd (ASX: RHT) (**Resonance** or **Company**) is pleased to release its preliminary results from the extended proof-of-concept (EPoC) stage of the DEVIMLA study of its non-invasive MRI liver fibrosis software as a medical device (**SaMD**). The results are also included in the investor presentation released today with the Company's \$6 million placement announcement.

Study Design

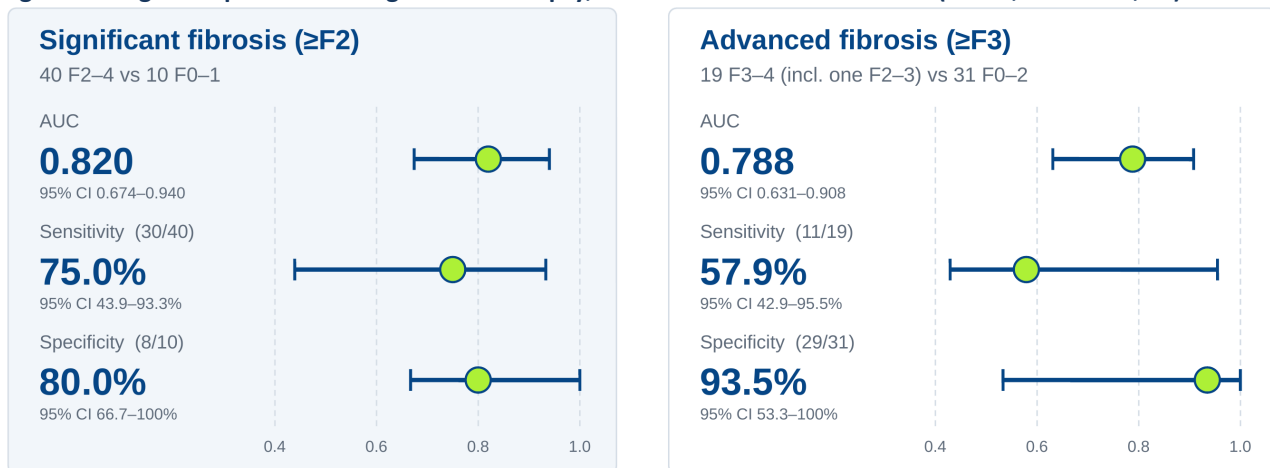
The EPoC stage of the DEVIMLA study enrolled 68 adults with biopsy-confirmed chronic liver disease at sites in Malaysia (University of Malaya), China and India (Indian Institute of Liver and Digestive Sciences). Each subject underwent a percutaneous liver biopsy, staged by an experienced pathologist, and an MRI examination acquiring three complementary image types.

The preliminary EPoC results are from the 50 subjects from the China site. All 50 subjects were recruited in China and represented a broad spectrum of clinical conditions, including liver cancer. Two initial classification models were developed; (i) one distinguishing no or mild fibrosis (F0–1) from significant fibrosis (F2–4), and (ii) the other distinguishing F0–2 from advanced fibrosis (F3–4).

All MRI examinations were performed at 3 Tesla (3T) on 3T MRI machines. Analysis at 3T is more technically challenging than at 1.5T which is the field strength used in the Company's 2022 proof-of-concept study. This is because magnetic susceptibility artefacts are more prevalent at higher field strengths. In addition, the 2022 study used a homogeneous population, whereas the current EPoC cohort encompasses a substantially wider range of clinical presentations and disease characteristics.

Preliminary Results

Figure 1: Diagnostic performance against liver biopsy, with 95% confidence intervals (n = 50, China site, 3T)



Sensitivity: share of biopsy-positive patients the model correctly identifies. Specificity: share of biopsy-negative patients it correctly rules out. AUROC: ability to separate the two groups across all cut-offs (0.5 = chance, 1.0 = perfect). Confidence intervals are wide because the groups are small, particularly the 10 subjects with F0–1 fibrosis. The results are preliminary, have not been independently verified and may change after independent pathology review, model refinement and the final study report. The device is investigational and not cleared for clinical use.

Results were generated using a first-pass model with intentionally limited parameters from one type of image analysis outcome. The 2022 proof-of-concept study (AUROC 0.92, 27 subjects) differentiated fibrosis from non-fibrosis and included healthy volunteers. The EPoC evaluated more demanding fibrosis classification endpoints in a broader and more clinically diverse population.

Resonance sees these results as a strong baseline and bona fide proof-of-concept which suggests that the FibrosisAssessment SaMD product can detect significant, advanced liver fibrosis.

Moving towards a greater AUROC Result

The current result represents an early stage of model development. The Company believes it can further enhance performance through ongoing analysis and methodological refinements, with all improvements evaluated through rigorous validation on independent datasets.

Reworking the model to improve accuracy does not require additional data or another study: it draws on data already collected in the DEVIMLA study. The full EPoC analysis will cover all 68 enrolled subjects, and validation of the final, locked model for regulatory submission will follow the pathway set out below.

Where the Device Sits?

The results point to strong potential for detecting earlier-stage fibrosis. For significant fibrosis, the first-pass AUROC of 0.82 is in line with the 0.82 reported for FibroScan which is used widely globally, by Cassinotto et al.¹ and consistent with the 2022 proof of concept. For advanced fibrosis, MR elastography (MRE) leads, with an AUROC of 0.91 in the LITMUS Imaging Study². Lifting advanced-fibrosis performance towards MRE is the current development focus. Figure 2 sets the first-pass results against published benchmarks³.

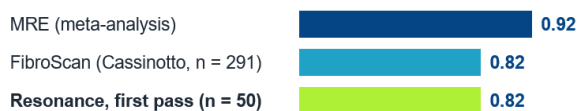
¹ Cassinotto C, et al. Liver stiffness in nonalcoholic fatty liver disease: a comparison of supersonic shear imaging, FibroScan, and ARFI with liver biopsy. *Hepatology* 2016;63:1817–1827 (FibroScan AUROC 0.82 for ≥F2 and 0.86 for ≥F3).

² Pavlides M, et al. Prospective validation of imaging and serum diagnostic biomarkers of steatohepatitis and fibrosis in MASLD: the LITMUS Imaging Study. *Nature Medicine* 2026;32:2959–2969 (n = 357; MRE AUROC 0.91 and iron-corrected T1 0.59 for advanced fibrosis).

³ Selvaraj EA, et al. Diagnostic accuracy of elastography and magnetic resonance imaging in patients with NAFLD: a systematic review and meta-analysis. *J Hepatol* 2021 (MRE summary AUROC 0.91 for ≥F2). Advanced fibrosis MRE and iron-corrected T1 from the LITMUS Imaging Study; FibroScan from Cassinotto et al. Park et al., *Gastroenterology* 2017 Cross-study comparison; indicative only

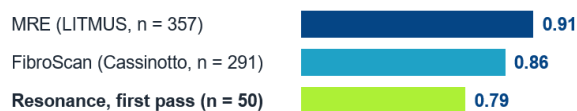
Figure 2: AUROC against liver biopsy, first-pass results versus published benchmarks

Significant fibrosis ($\geq F2$): AUC vs published benchmarks



Axis starts at 0.5 (chance).

Advanced fibrosis ($\geq F3$): AUC vs published benchmarks



Axis starts at 0.5 (chance).

Cross-study comparison involving different cohorts; indicative only. No head-to-head study has been performed. LITMUS did not report significant fibrosis ($\geq F2$) alone, so the $\geq F2$ MRE benchmark is from a different study: Park et al., Gastroenterology, 2017 Cross-study comparison; indicative only.

Unlike MRE and FibroScan, the Company's LiverAssessment device requires **no additional hardware or software** at the imaging site. It analyses standard MRI sequences generated images on existing 1.5T and 3T scanners and is delivered through the Company's ISO 13485-certified core laboratory. Matching MRE without the material MRE hardware investment is the opportunity.

The opportunity to be a biomarker benchmark in GLP-1 clinical trials

GLP-1 and related therapies are reshaping metabolic medicine, with several major agents in late-stage trials expanding into MASH, and semaglutide approved by the FDA for MASH in 2025. 951 obesity and overweight trials are listed on ClinicalTrials.gov⁴ and **sponsors increasingly need to measure the effect of treatment on the liver, not just on body weight.**

Many of these trials already scan the liver with MRI to measure liver fat, an endpoint Resonance provides through its regulatory-cleared HepaFatScan® and HepaFatSmart® products. Because the fibrosis device analyses standard MRI sequences, a non-invasive fibrosis biomarker could be added to those same assessments, with no additional hardware at the imaging site, through the same core laboratory. The Company intends to offer the LiverAssessment device for investigational use in pharma sponsors' clinical trials, building the paired MRI–biopsy dataset needed for regulatory validation.

Twenty Years of SaMD Development & Regulatory Clearance

The Company's non-invasive liver fibrosis R&D program builds on Resonance's deep expertise and established track-record in developing novel SaMDs and taking them through to regulatory clearances. Over 20 years, Resonance has developed and obtained regulatory clearances in the USA, Europe, the UK, and Australia for FerriScan®, internationally recognised as the gold standard in liver-iron-assessment, and for FerriSmart®, HepaFatScan®, HepaFatSmart®, LiverSmart® and CardiacT2*.

The Company's LiverAssessment SaMD follows the same pathway: complete the EPoC, refine the model, seek FDA Pre-Submission feedback, build the validation dataset through paid investigational use in pharmaceutical sponsors' trials, and conduct a pivotal validation ahead of an FDA 510(k) or De Novo submission for FDA clearance of the new SaMD.

What to Watch

The investor presentation, also released on ASX on 26 Oct 2026, sets out the catalysts for the next 12 to 24 months*. The LiverAssessment device and the Company's MRI endpoints for GLP-1, metabolic and obesity trials include:

- **Full EPoC analysis:** results for all 68 enrolled subjects;
- **Model refinement:** the reworked model, built on data already collected in the study and evaluated on independent data;
- **FDA Pre-Submission feedback:** on intended use, regulatory pathway, reference standard and validation design;

⁴ ClinicalTrials.gov data as summarised by Data Lookout, March 2026 (951 trials tagged obesity or overweight); US FDA approval of semaglutide for MASH (2025).

- **First investigational-use contracts:** paid analysis of fibrosis (for investigational use) in pharmaceutical sponsors' clinical trials;
- **Muscle quality endpoints to market and VAT/SAT automation live:** completing the obesity-trial imaging protocol; and
- **First Image Analysis Group (IAG) work orders:** pilot studies through the Company's global imaging partner (see ASX release 17 Sep 2026).

**Catalysts and timing are not guaranteed.*

Resonance Health's CEO & Managing Director, Mr Andrew Harrison said:

"These preliminary results are a very encouraging step towards commercialising the FibrosisAssessment device in GLP-1 clinical trials. Separating fibrosis stages this well in a challenging, heterogeneous cohort, on 3T data where artefacts are more prevalent, from a first-pass model with intentionally limited parameters is a strong start.

Importantly, we now have a baseline to improve the model accuracy using data we already hold, without another trial. With GLP-1 and metabolic trials already scanning the liver, a fibrosis biomarker from standard MRI with no added hardware opens a real opportunity with sponsors, and taking SaMDs from development through to regulatory clearance is what Resonance has done for 20 years."

Resonance Health's Chief Scientific Officer, Dr Wenjie Pang said:

"A clear fibrosis signal was identified at 3T, the more demanding field strength, in a broad and clinically diverse cohort, using a first-pass model with intentionally limited parameters. We see potential to further enhance performance through ongoing analysis and methodological refinements of the study data, with every improvement evaluated through rigorous validation on independent datasets."

The investor presentation released to ASX today includes these results.

To watch Mr Harrison's video presentation, please visit the Company's InvestorHub:

<https://investors.resonancehealth.com/link/yMdo5P>

Further Information

<https://investors.resonancehealth.com>

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

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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-trained, non-invasive MRI-based device for the automated real-time assessment of LIC in participants, calibrated against the global gold standard, FerriScan®.
- **HepaFatScan®**, 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.
- **HepaFatSmart®**, an AI-trained, non-invasive device for the automated real-time multi-metric assessment of liver-fat in participants, for the assessment of individuals with confirmed or suspected fatty liver disease.
- **LiverSmart®**, an AI-trained, 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*.

The Company has a development pipeline of additional medical imaging analysis products and services, including the MRI Liver Fibrosis Project, aimed at accurately assessing the presence and progression of liver fibrosis utilising non-invasive MRI analysis. The Company also has a clinical trials business which both manages clinical trials in Australia and includes the site management operations of TrialsWest.

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

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This announcement has been prepared by Resonance Health Ltd ("Resonance Health" or "Company") and may contain forward-looking statements that are based on current expectations and beliefs and are subject to numerous factors and uncertainties that could cause actual results to differ materially from those described. Forward looking statements contained in this release may include statements about future financial and operating results, status of regulatory submissions, possible or assumed future growth opportunities and risks and uncertainties that could affect Resonance Health's products and services.

These forward-looking statements are not guarantees of future performance, involve certain risks, uncertainties and assumptions that are difficult to predict, and are based upon assumptions as to future events that may prove inaccurate. Actual outcomes and results may differ materially from what is expressed in any forward-looking statement in which Resonance Health expresses an expectation or belief as to future results. There can be no assurance that the statement or expectation or belief will result or be achieved or accomplished. Resonance Health will not update forward-looking statements unless required by law.