
MRI LIVER FIBROSIS DEVICE CLINICAL TRIAL PRELIMINARY RESULTS WEBINAR

Resonance Health Ltd (Resonance or Company) (ASX: RHT) has today released “**Preliminary results of MRI Liver Fibrosis Device clinical trial investor presentation**”, enclosed with this announcement.

Investors are invited to join a webinar hosted by Andrew Harrison, MD & CEO and Dr Wenjie Pang, Chief Scientific Officer on Wednesday 28th October 2026 at 10:00 a.m. Australian Western (Perth) Time (AWST).

Andrew Harrison, MD & CEO said; “*I invite you to join us for the release of our positive preliminary results from our MRI liver fibrosis device clinical trial as we talk through the trial, methods and key outcomes*”.

You can attend via the link:

<https://investors.resonancehealth.com/webinars/yEMgGy-mri-liver-fibrosis-device-clinical-trial-preliminary-results-webinar>

Additionally, a video recording of the presentation will be available within 24 hours following the presentation at the **Resonance Health Investor Centre homepage:**

<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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PRELIMINARY EPOC STUDY RESULTS | OCTOBER 2026

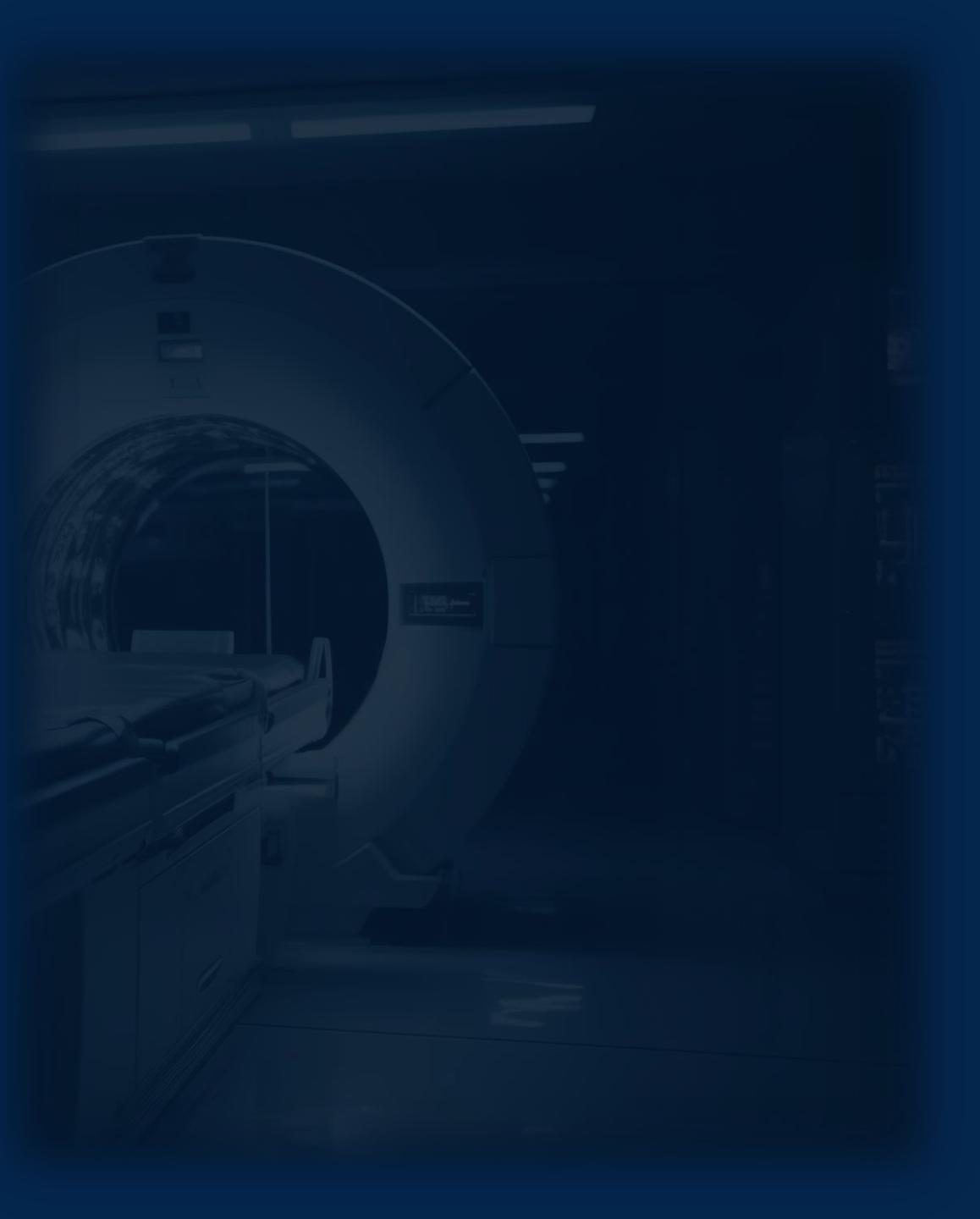
Liver fibrosis results open GLP-1 biomarker opportunity

FibrosisAssessment: non-invasive MRI liver fibrosis
software as a medical device

Andrew Harrison | MD & CEO

Dr Wenjie Pang | Chief Scientific Officer

Resonance Health Ltd (ASX:RHT)



Important notice and disclaimer

Preliminary results. Liver fibrosis results are preliminary and not yet independently verified, based on 50 subjects from a single site representing a broad spectrum of clinical conditions including liver cancer, and may change as additional data becomes available. FibrosisAssessment is investigational and not cleared for clinical use in any jurisdiction.

Compiled by. The extended proof-of-concept (EPoC) study was performed by Dr Wenjie Pang, Chief Scientific Officer of Resonance Health. Dr Pang's qualifications and experience are set out at www.resonancehealth.com/board-leadership.

Comparisons. Comparisons with other tests draw on published studies in different cohorts and are indicative only. No head-to-head study has been performed.

Market estimates and economics. Market sizes, pricing, trial sizes and scan volumes are illustrative Company estimates built from the sources shown. They are not forecasts. FY27 guidance excludes revenues that may accrue from the fibrosis device.

Forward-looking statements. This presentation contains forward-looking statements that involve risks and uncertainties; actual outcomes may differ materially. See the full disclaimer at the end of this presentation.

Not advice. This presentation does not take into account the objectives, financial situation or needs of any person. Investors should seek independent professional advice.

A fibrosis signal from standard MRI

Preliminary EPoC read-out: 50 biopsy-confirmed subjects scanned at 3T, against liver biopsy



0.82

AUROC, significant fibrosis (≥F2)

In line with FibroScan (0.82)



93.5%

Specificity, advanced fibrosis (≥F3)

A rule-in operating point



US\$0

Added hardware or software

at the imaging site



951

Obesity and overweight trials

The GLP-1 biomarker opportunity

A first-pass model with intentionally limited parameters. Refining it uses data already collected in the study, so no additional data or new study is needed, and every improvement will be validated on independent data.

Sources: Company preliminary analysis (n = 50, China site, 3T); Cassinotto et al., Hepatology 2016 (FibroScan); ClinicalTrials.gov via Data Lookout (March 2026).

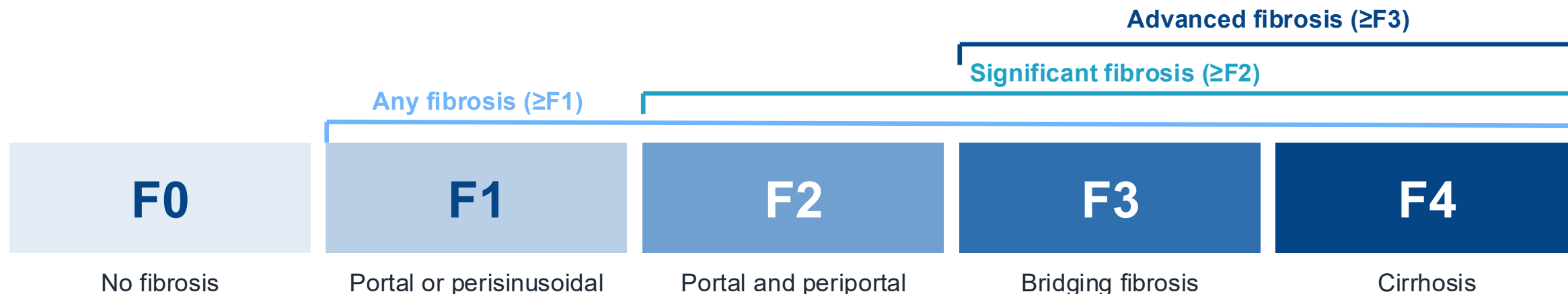
01

The opportunity

Why liver fibrosis matters in GLP-1, metabolic and obesity trials



Fibrosis stage is what trials and payers need to know



Today: a needle biopsy

Liver biopsy remains an imperfect gold standard due to sampling variability, reader variability and procedure burden, highlighting the need for robust non-invasive biomarkers



Why it matters

Reliable, reproducible, and clinically meaningful non-invasive endpoints can support clinical trial efficacy assessments, reduce dependence on invasive procedures, and strengthen evidence for regulatory decision-making



What FibrosisAssessment does

Classifies $\geq F1$, $\geq F2$ and $\geq F3$ from standard MRI (PoC and EPoC) Non-invasive, MRI-based without contrast agent or added hardware (investigational).

Fibrosis stages simplified from NASH CRN and METAVIR conventions. Sources: Hsu et al., pooled individual-participant analysis, 2019 (mortality and fibrosis stage); LITMUS Imaging Study protocol (biopsy variability).

Biopsy gates MASH trials, and most fail it

70–80%

of patients screened for MASH trials fail screening, mostly because the baseline biopsy does not show fibrotic MASH



Roughly 2 to 3 in every 10 screened patients enrol



Invasive and imprecise

Needle biopsy, an imperfect reference standard, carries procedural risk, samples a tiny fraction of the liver and is subject to sampling and reader variability.



Regulators are moving

In 2025 the FDA accepted the first Letter of Intent to qualify liver stiffness measured by VCTE (FibroScan) as a reasonably likely surrogate endpoint in MASH. MRE was subsequently accepted into the FDA Biomarker Qualification Program, signalling growing support for non-invasive fibrosis endpoints.



Sponsors need scale

With two MASH drugs FDA-approved now, trials and therapies need a scalable, repeatable, and clinically meaningful fibrosis assessments to support patient selection, endpoint evaluation, and treatment monitoring.

Sources: MASH trial screening analysis, PMC11985113; LITMUS Imaging Study protocol; FDA CDER statement, 27 Aug 2025; HCPLive 2025 (semaglutide approval).

Three structural tailwinds

Independent forces converging on the capabilities Resonance Health has spent 20 years building

01

Liver disease prevalence

1.5B+

people living with chronic liver disease

- 20%+ of the global population; 58M+ new cases a year
- MASLD affects about one in four adults; demand for screening, trial enrolment and monitoring is structural

02

MASH diagnostics demand

2

FDA-approved MASH therapies since 2024

- Resmetirom (2024) and semaglutide (2025): every patient needs or benefits from fibrosis staging and monitoring
- Payers may require biopsy or a non-invasive test before covering therapy; the biopsy is the bottleneck

03

GLP-1 trial explosion

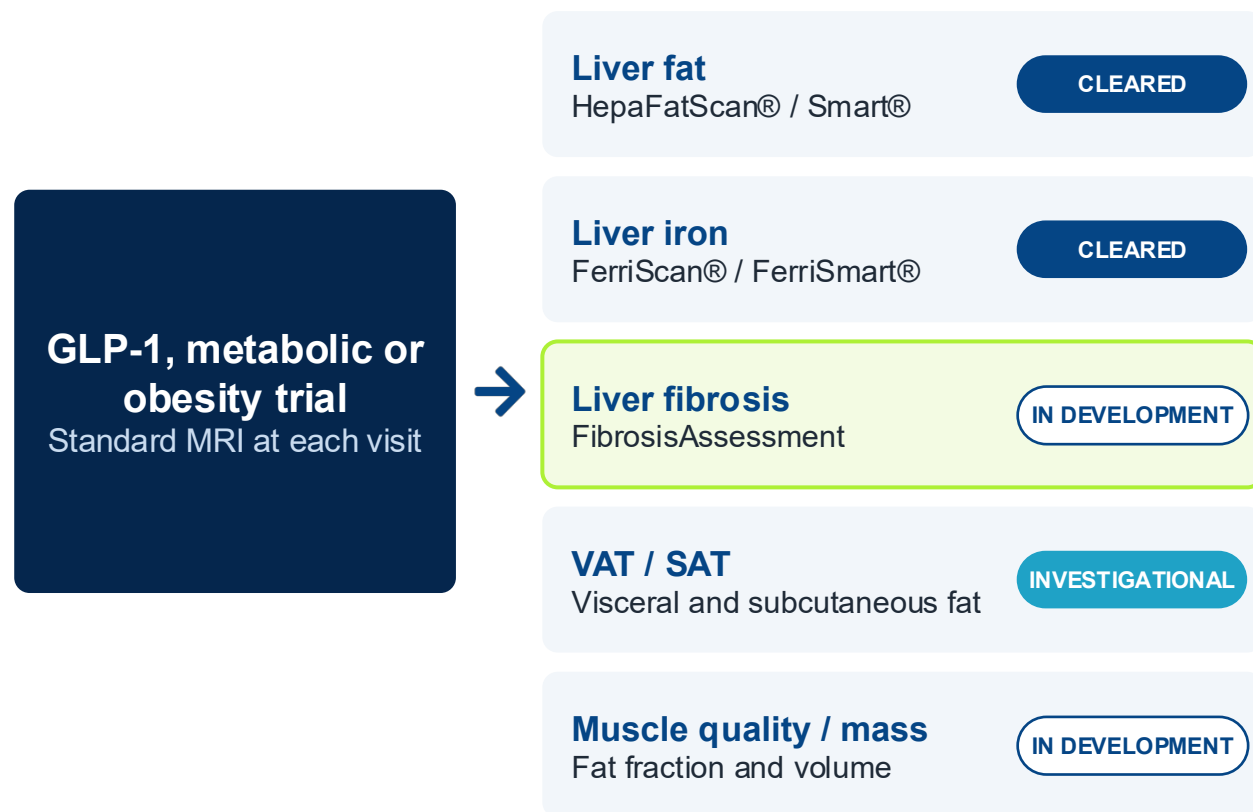
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obesity and overweight trials listed

- 6+ major GLP-1 agents in late-stage trials, expanding into MASH, HFpEF and CKD
- Sponsors need body composition, not just weight: liver fat, fibrosis, VAT/SAT and muscle

Sources: Company FY26 results presentation (liver disease prevalence); HCPLive 2025 (semaglutide approval); payer prior-authorisation criteria; ClinicalTrials.gov via Data Lookout (March 2026).

One MRI visit, the full GLP-1 read-out



- **Fibrosis is a key endpoint**

Fibrosis is a key biomarker endpoint in GLP-1, metabolic and obesity trials, particularly following the FDA approvals of resmetirom and semaglutide for MASH in 2024 and 2025, respectively.

- **The scans already happen**

Many trials already scan the liver with MRI to measure fat. A fibrosis read can be added to the same images, through the same core lab.

- **We are already inside the trial**

TrialsWest is running multiple GLP-1 and metabolic trials, and the Image Analysis Group alliance gives sponsors global access.

One scan, one ISO 13485 core lab, no added hardware at the imaging site

Sources: Company; ClinicalTrials.gov via Data Lookout (March 2026); US FDA approval of semaglutide for MASH (2025); IAG announcement (ASX, 17 Sep 2026). FibrosisAssessment is in development and investigational.

Standard MRI in, fibrosis read out



The same core-lab model as FerriScan®, HepaFatScan® and others, already used by clinicians and in pharmaceutical trials worldwide.

1

Scan

Standard sequences on any modern 1.5T or 3T scanner. No contrast injection, no added hardware, no site software.

2

Upload

DICOM images sent securely through the core-lab workflow used for FerriScan® and HepaFatScan®.

3

Analyse

Proprietary analysis of the liver's MRI signal, built on 20 years of iron- and fat-corrected liver MRI.

4

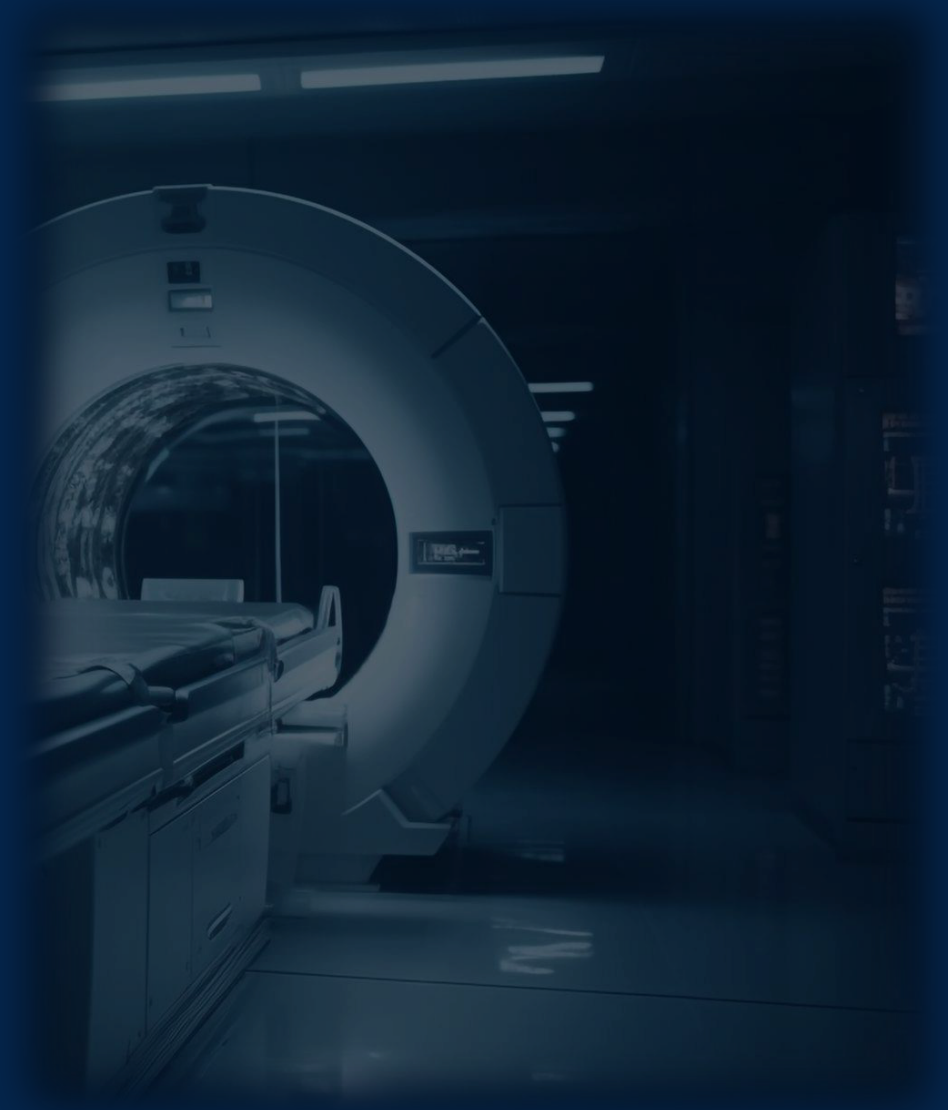
Report

Fibrosis classification against biopsy-defined stages. Images are archived, auditable and re-analysable.

02

The results

Preliminary results from the extended proof-of-concept study (EPoC)



DEVIMLA extended study: what was analysed

Development and Validation of Multiparametric MRI for Non-Invasive Measurement of Liver Fibrosis and Activity

● Study

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). Percutaneous biopsy, staged by an experienced pathologist, is the reference.

● This read-out

50 subjects from the China site, representing a broad spectrum of clinical conditions, including liver cancer. All MRI examinations at 3T. One initial classification model.

● Endpoints

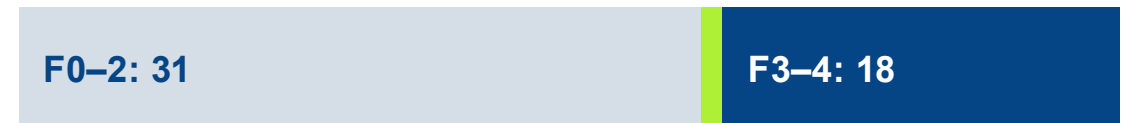
Significant fibrosis (F0–1 vs F2–4) and advanced fibrosis (F0–2 vs F3–4) against biopsy stage.

Biopsy stage distribution, n = 50

Significant fibrosis model ($\geq F2$)



Advanced fibrosis model ($\geq F3$)



Plus one borderline case staged F2–3 (lime)

3T is more technically challenging than 1.5T because magnetic susceptibility artefacts are more prevalent. The 2022 proof of concept used 1.5T in a homogeneous NAFLD/NASH population.

Unlocking fibrosis signal from standard MRI

Significant fibrosis ($\geq F2$)

40 F2–4 vs 10 F0–1

AUC

0.820

95% CI 0.674–0.940

Sensitivity (30/40)

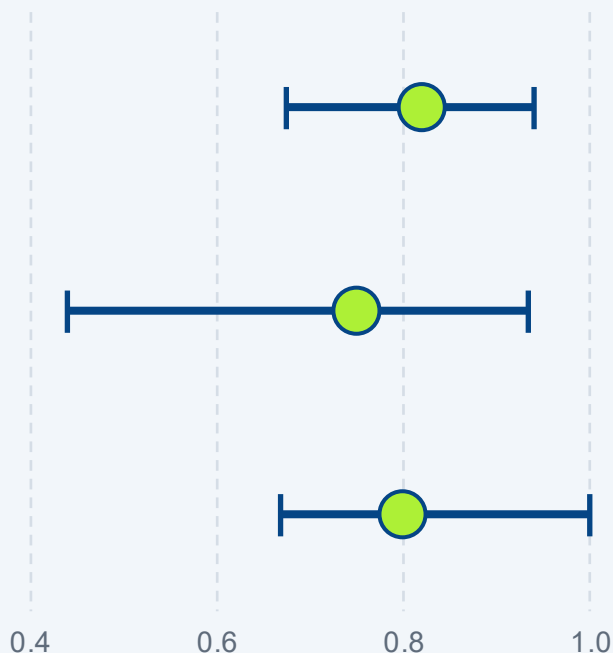
75.0%

95% CI 43.9–93.3%

Specificity (8/10)

80.0%

95% CI 66.7–100%



Advanced fibrosis ($\geq F3$)

19 F3–4 (incl. one F2–3) vs 31 F0–2

AUC

0.788

95% CI 0.631–0.908

Sensitivity (11/19)

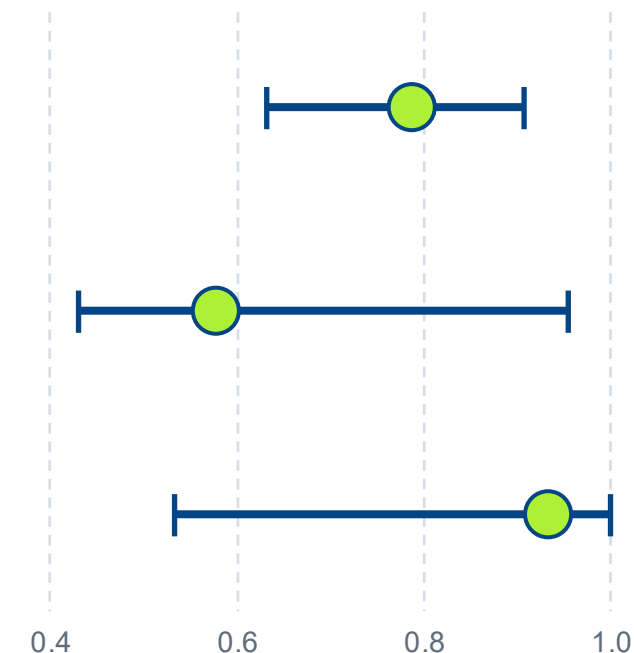
57.9%

95% CI 42.9–95.5%

Specificity (29/31)

93.5%

95% CI 53.3–100%



Sensitivity: proportion of biopsy-positive subjects correctly identified. **Specificity:** proportion of biopsy-negative subjects correctly excluded. **AUC:** ability to distinguish the two groups across all cut-offs (0.5 = chance, 1.0 = perfect). **95% CI:** range likely to contain the true value.

DEVIMLA EPoC interim analysis: 50 of 68 enrolled subjects (China site, 3T), first-pass model. Preliminary; subject to further analysis and independent verification.

What the numbers say, and what they don't yet



A real signal

The model separates fibrosis stages well above chance, at both thresholds, on 3T data, from a first-pass model with intentionally limited parameters.



Expands the 2022 PoC

The 2022 PoC (AUC 0.92, n = 27) separated fibrosis from non-fibrosis, including healthy volunteers. The EPoC tests more demanding endpoints in a more diverse population.

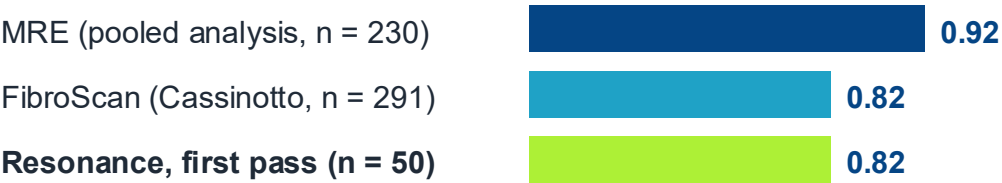


Small cohort, wide intervals

With 10 F0–1 subjects, specificity for $\geq$ F2 rests on few patients. The validation study is sized to narrow these intervals.

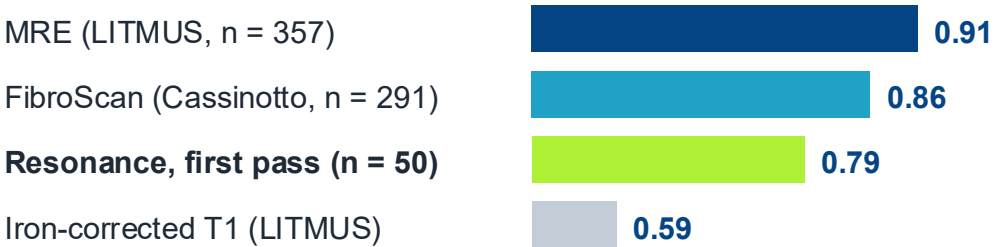
Strong potential for early-stage fibrosis detection, in line with FibroScan and the 2022 PoC; lifting advanced-fibrosis performance towards MR elastography is the current development focus. Matching it without the hardware investment is the opportunity.

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).

Benchmarks: $\geq$ F2 MRE, Hsu et al. 2019, pooled individual-participant analysis of three studies including Park et al., Gastroenterology 2017 (n = 230); $\geq$ F3 MRE and cT1, Pavlides et al., Nat Med 2026 (LITMUS; $\geq$ F2 not reported); FibroScan, Cassinotto et al., Hepatology 2016. Cross-study; indicative only.

Towards a greater AUROC, without a new study

The current result represents an early stage of model development

NOW

First-pass model

Intentionally limited parameters, 50 subjects at 3T: AUROC 0.82 ($\geq F2$) and 0.79 ($\geq F3$).



NEXT

Refined model

Ongoing analysis and methodological refinements, using data already collected in DEVIMLA, with the full EPoC analysis covering all 68 subjects.



THEN

Locked and validated

Every improvement evaluated through rigorous validation on independent datasets, then pivotal validation for the FDA submission.

No additional data or new study needed. Reworking the model to improve accuracy draws on data already collected in the DEVIMLA study. Validation of the final, locked model for regulatory submission then follows the FDA pathway set out later in this presentation.

03

Where it sits

Access, positioning and the market opportunity

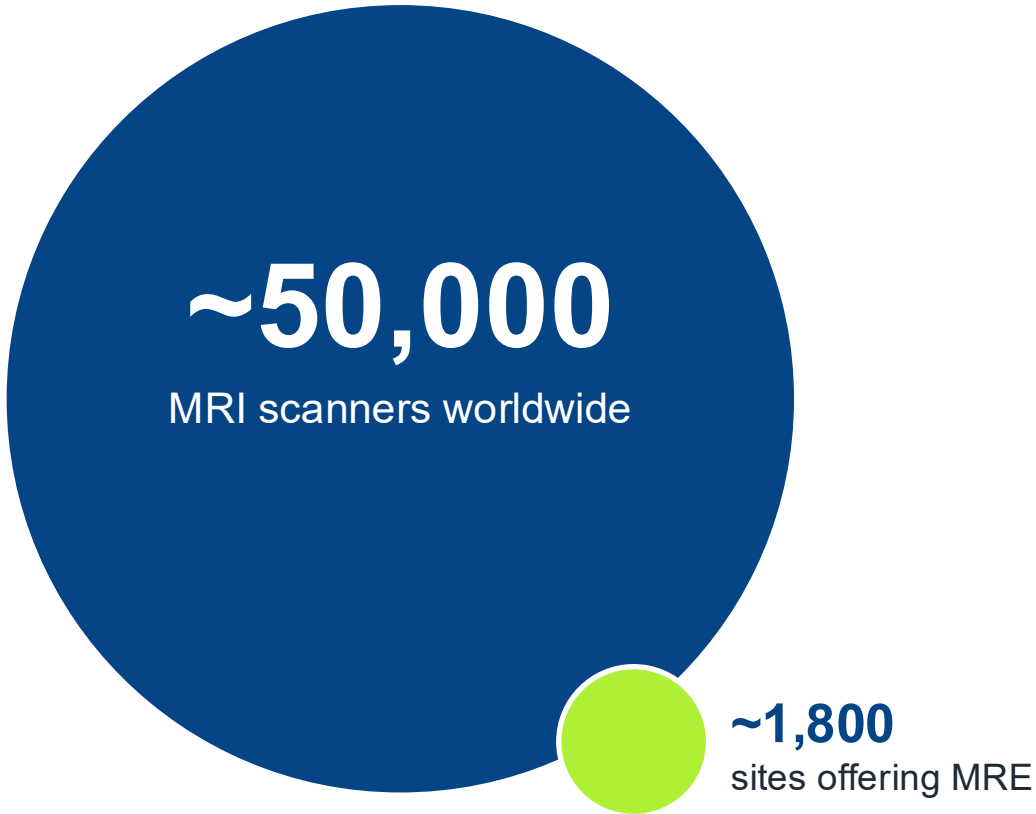


FibrosisAssessment versus MRE and FibroScan

	FibrosisAssessment (MRI)	MR elastography (MRE)	FibroScan (VCTE)
Added equipment at site	None: standard MRI sequences	Driver hardware, sequence and software licence	Dedicated ultrasound device and probes
Capex per site	US\$0	~US\$75k–150k per scanner	~US\$70k–125k per device
Availability	Any modern 1.5T or 3T MRI (~50,000 worldwide)	~1,800 sites worldwide	Specialist clinics, trained operator at each site
Operator dependence	Central core-lab analysis	Operator-dependent	Operator-dependent
Known limits	Investigational; validation pending	Fails with liver iron overload, unreliable in severe obesity, inflammation and ascites	Fails with liver iron overload, unreliable in severe obesity, inflammation and ascites
Images for central re-read	Yes, archived DICOM	Yes	No anatomical images captured
Evidence today (AUROC)	Preliminary: 0.82 (≥F2), 0.79 (≥F3); n = 50	0.92 (≥F2, pooled); 0.91 (≥F3, LITMUS)	0.82 (≥F2), 0.86 (≥F3), Cassinotto; FDA letter of intent accepted 2025

Sources: Resoundant; Post-Bulletin and Company (MRE cost); published estimate and Company (FibroScan cost); Diagnostic Imaging (MRE and iron); AJR 2015 (VCTE limits); Hsu et al. 2019; Pavlides et al., Nat Med 2026; Cassinotto et al., Hepatology 2016; FDA CDER, Aug 2025. Cross-study comparisons are indicative only.

Mass access at zero capex for imaging sites



~50,000
MRI scanners worldwide

~1,800
sites offering MRE

Circle areas to scale.

US\$0

FibrosisAssessment: no added hardware or software at the imaging site

US\$75k–150k

MRE: per scanner, for driver hardware, sequence and software licence

US\$70k–125k

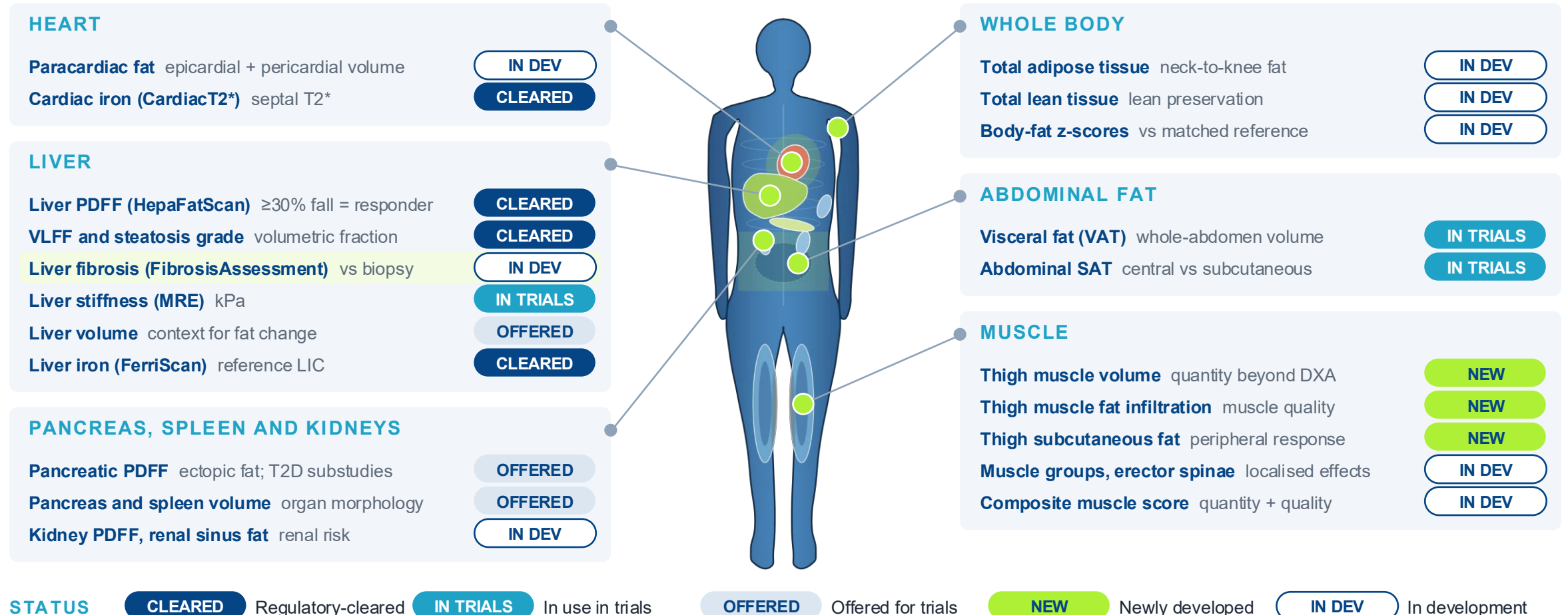
FibroScan: per device, plus a trained operator at each site

Machine-agnostic by design: standard sequences on existing 1.5T and 3T scanners, delivered through the Company's ISO 13485-certified core lab.

Sources: StartUs Insights (MRI base, 2022 est.); Resoundant (MRE sites); Post-Bulletin and Company (MRE cost); published estimate and Company (FibroScan cost).

FibrosisAssessment completes the liver read-out

Metabolic and obesity MRI trial endpoints, grouped by region, from one imaging session and one ISO 13485 core lab



Three markets, entered in sequence

US context: ~460,000 diagnosed F2–F3 MASH patients under specialist care; 6.7M adults with MASH and $\geq$ F2 fibrosis; 267 MASH trials recruiting.

STAGE 1 | NOW

Clinical trials

Investigational use in pharma MASH, GLP-1 and obesity trials. No FDA clearance or reimbursement needed, and it builds the FDA dataset needed for clearance.

Paid by sponsors, per scan

STAGE 2 | POST-CLEARANCE

Clinical diagnostics

Launch through hepatology centres and the imaging sites globally already using FerriScan® and HepaFatScan®.

Paid by providers, patients and some payers

STAGE 3 | POST-COVERAGE

Reimbursed diagnostics

Payer coverage, naming in MASH-drug prior-authorisation criteria alongside VCTE and MRE, then a Category I CPT code.

Paid by insurers, at population scale

Sources: Madrigal Q2 2026 call; Le et al., JAMA Netw Open 2025; ClinicalTrials.gov via Data Lookout (May 2026). Stage timing depends on FDA clearance and payer decisions.

Illustrative investigational-use economics per trial

Revenue = price per scan × patients × MRI visits

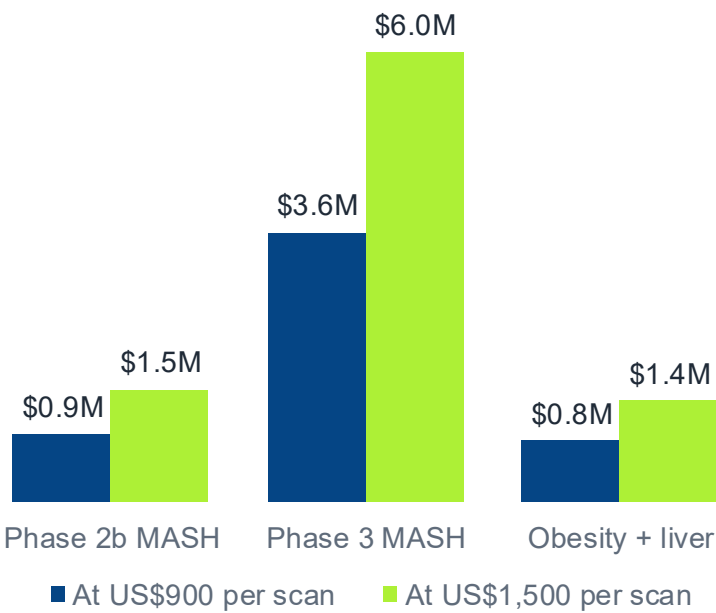
Indicative economics for three prevalent trial types

Trial type	Patients	MRI visits	Scans	Revenue at US\$900–1,500*	Paired biopsy cases
Phase 2b MASH	250	4	1,000	US\$0.9M–1.5M	~465
Phase 3 MASH	1,000	4	4,000	US\$3.6M–6.0M	~1,860
Obesity trial, liver sub-study	300	3	900	US\$0.8M–1.4M	—

* Price per scan

Excludes trial management, data management, reporting and other fees routinely charged to sponsors

Revenue per trial (US\$M)

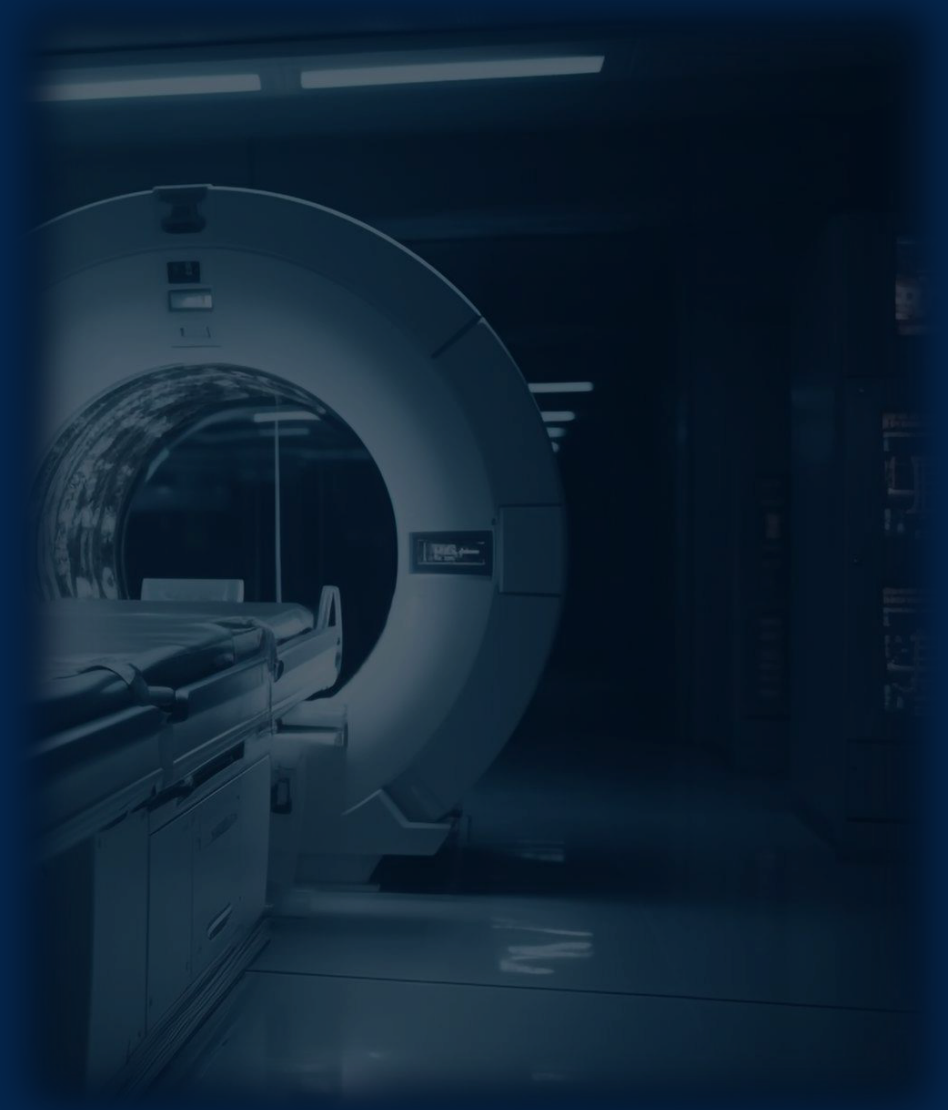


Illustrative assumptions, not forecasts. Pricing range per Company; trial sizes and visit schedules vary by sponsor. Paired cases assume biopsy at baseline and end of treatment with ~86% completion. FY27 guidance includes no fibrosis device revenue.

04

Path to FDA

Twenty years of SaMD development and regulatory clearance



Twenty years of SaMD development and clearance

FibrosisAssessment follows the path Resonance has taken with its regulatory-cleared SaMDs

FerriScan®

CLEARED

Core-lab liver iron concentration; internationally recognised as the gold standard in LIC assessment

FerriSmart®

CLEARED

AI-trained, automated real-time liver iron, calibrated against FerriScan®

HepaFatScan®

CLEARED

Reliable non-invasive assessment of liver fat for confirmed or suspected fatty liver disease

HepaFatSmart®

CLEARED

AI-trained, automated real-time multi-metric assessment of liver fat

LiverSmart®

CLEARED

Liver iron and liver fat combined in one consolidated report

CardiacT2*

CLEARED

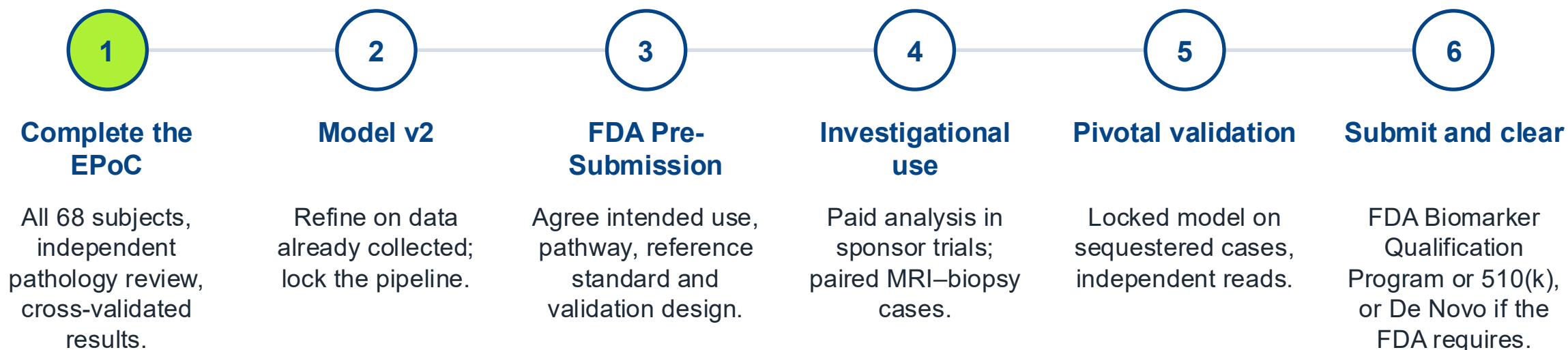
The most widely accepted MRI method for assessing heart iron loading

Cleared in the USA, Europe, the UK and Australia | ISO 13485 certified | **FibrosisAssessment follows the same pathway**

Regulatory-cleared SaMD products, some of which incorporate AI. ISO 13485 certification covers the design and manufacture of medical devices.

From preliminary results to an FDA submission

We are here



Capital-light by design: model development, the FDA Pre-Submission and the regulatory files are funded from the balance sheet, while sponsors pay for the scans that build the validation dataset, at US\$900–1,500 per scan.

Subject to FDA feedback. FDA review goals: Pre-Submission feedback 70 days; 510(k) 90 FDA days; De Novo 150 FDA days.

What to watch over the next 12 to 24 months



FibrosisAssessment

- **Full EPoC analysis**
results for all 68 enrolled subjects
- **Model refinement**
built on data already collected and evaluated on independent data
- **FDA Pre-Submission feedback**
intended use, pathway, reference standard and validation design
- **First investigational-use contracts**
paid fibrosis analysis in sponsors' trials



The GLP-1 imaging protocol

- **Muscle quality endpoints to market**
completing the obesity-trial imaging protocol
- **VAT/SAT automation live**
more throughput and margin on body-fat reads
- **First Image Analysis Group work orders**
pilot studies through the global imaging partner (ASX, 17 Sep 2026)

Catalysts and timing are not guaranteed.

A very encouraging step, with a clear path to improve

“

“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.”



Andrew Harrison
Managing Director & CEO

“

“A clear fibrosis signal was identified at 3T consistent with the 1.5T proof-of-concept result, despite the more demanding field strength, in a broad and clinically diverse cohort, using a simple first-pass model with intentionally limited parameters. We see believe 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.”



Dr Wenjie Pang
Chief Scientific Officer

Quotes from the ASX announcement “Liver Fibrosis Results Open Up GLP-1 Biomarker Opportunity”, 27 October 2026.

Key risks

- **Clinical validation:** Preliminary results may not be confirmed in the full and final EPoC analysis or in validation.
- **Regulatory:** The FDA pathway (510(k) or De Novo), timing and outcome are uncertain; the FDA may require more data.
- **Commercial adoption:** Sponsors may not adopt an investigational fibrosis read, or may prefer established tests.
- **Competition:** MRE, VCTE and other MRI methods compete, and may improve.
- **Model refinement:** Planned refinements may not improve performance as expected.
- **Data rights:** The validation dataset depends on sponsors agreeing to the use of paired MRI–biopsy data.
- **Reimbursement:** There is no assurance of coding, coverage or payment for diagnostic use.
- **People:** Performance depends on retaining key scientific and commercial staff.

Not an exhaustive list. Investors should consider all information in this presentation, including the forward-looking statements, and seek professional advice.

Summary

- 1 A real fibrosis signal from standard MRI: AUROC 0.82 for $\geq F2$, in line with FibroScan, and 0.79 for $\geq F3$.
- 2 Achieved at 3T in a challenging, heterogeneous cohort, from a first-pass model.
- 3 Refinement uses data already collected: no additional data or new study needed.
- 4 No hardware at the scanner: built for GLP-1, metabolic and obesity trials that already scan the liver.
- 5 Trials first, then diagnostics, then reimbursement, on a 20-year SaMD track record.

Andrew Harrison, Managing Director & CEO

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Glossary

AUROC (AUC) Area under the ROC curve: ability to separate two groups across all cut-offs (0.5 = chance, 1.0 = perfect).

Sensitivity Proportion of biopsy-positive subjects the model correctly identifies.

Specificity Proportion of biopsy-negative subjects the model correctly rules out.

95% CI Confidence interval: the range likely to contain the true value; intervals are typically wider when sample sizes are small.

F0–F4 Biopsy fibrosis stage (METAVIR), from none (F0) to cirrhosis (F4). Significant is $\geq$ F2; advanced is $\geq$ F3.

MASLD / MASH Metabolic dysfunction-associated steatotic liver disease and steatohepatitis (formerly NAFLD / NASH).

GLP-1 GLP-1 receptor agonists: a drug class for obesity and type 2 diabetes, now expanding into MASH.

MRE Magnetic resonance elastography: liver stiffness measured with driver hardware and software added to the scanner.

VFTE (FibroScan) Vibration-controlled transient elastography: an ultrasound-based liver stiffness device.

cT1 Iron-corrected T1: an MRI measure of liver tissue characteristics.

1.5T / 3T MRI field strength in tesla. 3T gives more signal but more susceptibility artefacts.

SaMD Software as a medical device: software with a medical purpose, regulated as a device.

EPoC / DEVIMLA The extended proof-of-concept stage of Resonance's DEVIMLA liver fibrosis study.

510(k) / De Novo FDA clearance routes: with a predicate device (510(k)) or for novel low-to-moderate risk devices (De Novo).

Investigational use Use of a device in clinical trials before clearance, where results are not used for patient care.

FDA Biomarker Qualification Program A formal regulatory pathway that qualifies biomarkers for specific contexts of use (COU) in drug development.

DISCLAIMER

Disclaimer and forward-looking statements

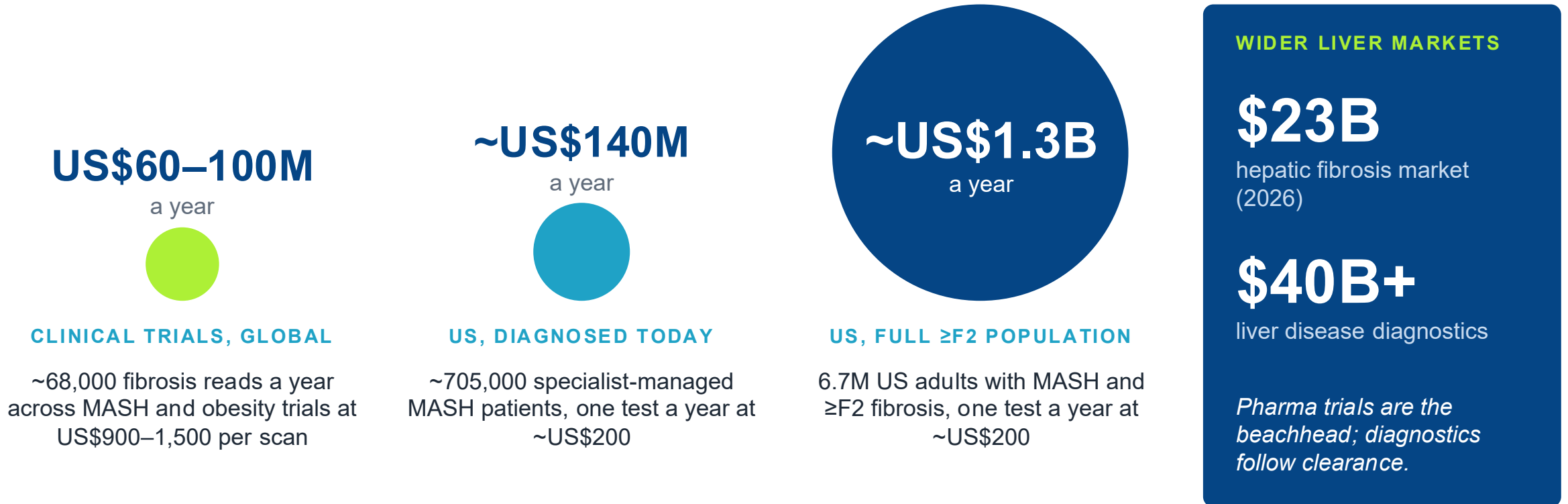
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A trial beachhead inside a much larger market

Liver fibrosis assessment, annual market by stage



Company estimates, not forecasts; bubble areas to scale. Trials: ~16 Phase 3 and ~40 industry Phase 2 MASH trials plus obesity imaging cohorts (~68,000 scans/yr). Diagnostics at the 2026 Medicare MRE rate (CPT 76391, ~US\$197). Sources: Data Lookout; Madrigal Q2 2026; Le et al., JAMA Netw Open 2025; Company FY26 results presentation.