

# Transforming Breast Health Through Imaging Intelligence

**SNAPSHOT:** The first FDA-cleared breast imaging platform combining anatomic and functional breast imaging with quantitative transmission ultrasound. We are building a future where diagnostic imaging is objective, AI and biomarkers driven and available without discomfort, radiation, or contrast agents.

From HW company to a sustainable, scalable, data-centric ecosystem continuously improving with clinical use, with a business model that combines:

- Innovative, FDA-cleared breast imaging scanner
- Advanced image reconstruction software
- Quantitative biomarkers such as speed-of-sound, breast density (fibroglandular ratio), attenuation, reflection parameters, etc
- A layered Cloud SaaS Platform revenue with continuous feature updates and near zero on-premise installation burden

This transition unlocks recurring revenue, clinical standardization and precision imaging at scale.

## The Problem

### Current Standard of Care Challenges

- **Low Compliance:** 35% of women avoid regular breast screening
- **High Recall Rates:** ~15% callback rate; 98% of recalls are avoidable
- **Unnecessary Biopsies:** Over 80% of biopsies from callbacks are benign
- **Dense Breast Limitations:** Mammography can miss ~35–52% of cancers in dense tissue

## The QTI Solution

### Quantitative Transmission Imaging

A new category of true 3D, high resolution, quantitative ultrasound-based imaging

- **3D Volumetric Imaging:** Uses CT-like configuration with ultrasound to map speed-of-sound across tissue volume
- **MRI-like Resolution:** Achieved without contrast agents and without the enclosed environment associated with MRI
- **Consistent & Standardized Imaging:** Overcomes operator dependence and lack of standardization seen with handheld ultrasound
- **Safe & Comfortable:** Pain free; no radiation; no breast compression; no contrast injection

|                       | QT Scan                          | HHUS  | CE-MRI   | XRM/DBT   | Breast CT   |
|-----------------------|----------------------------------|---|--|---|---|
| Underlying Technology | Ultrasound                       | Ultrasound  | Magnetic Resonance   | X-Ray   | X-Ray   |
| Image Quality         | ●                                | ●   | ●  | ●   | ●   |
| Safety <sup>(1)</sup> | ●                                | ●   | ●  | ●   | ●   |
| Cost Efficiency       | ●                                | ●   | ●  | ●   | ●   |
| Patient Experience    | ●                                | ●   | ●  | ○   | ●   |
|                       | <b>The QTI Imaging Advantage</b> | <b>...OVER HHUS</b> <ul style="list-style-type: none"> <li>• Superior image quality</li> <li>• Not operator dependent</li> <li>• Quantifiable/repeatable</li> </ul> | <b>...OVER MRI</b> <ul style="list-style-type: none"> <li>• High resolution and contrast-to-noise ratio</li> <li>• No injection needed</li> <li>• Lower equipment cost</li> <li>• No special facility or shielding requirements</li> </ul> | <b>...OVER XRM/DBT</b> <ul style="list-style-type: none"> <li>• Improved image quality</li> <li>• Safer (no radiation), allowing for more frequent imaging</li> <li>• Greater specificity</li> <li>• No special facility requirements</li> <li>• Quantifiable/repeatable</li> </ul> | <b>...OVER BREAST CT</b> <ul style="list-style-type: none"> <li>• No radiation – breast CT radiation is significantly higher than screening mammography</li> <li>• No contrast needed (compared to contrast enhanced CT)</li> </ul> |

## Clinical Value Overview

High-quality imaging for dense breasts powered by quantitative geometric, spectral and elastic biomarkers will allow for:

- **Radiologists** obtain standardized, quantitative imaging with fewer false positives and improved assessment in dense breasts
- **Oncologists** to benefit from biomarkers that support therapy monitoring and treatment planning
- **Breast surgeons** to get clearer lesion characterization to inform surgical decisions
- **Primary care physicians** to offer a safe, comfortable imaging option that improves screening compliance and reduces unnecessary callbacks

## Regulatory Advancements

- Saudi FDA regulatory approval anticipated in Q2'26
- UAE MOHAP submission
- CE Mark certification targeted for Q4 2026

## Reimbursement Pathway Progress

- **Breakthrough Device Designation** supports faster pathways for new reimbursement codes and future clearances
- New Technology APC application submitted with expected temporary payment assignment in Q1'26
- Category III CPT code application submitted with expected assignment in Q1 2027
- Current use supported through **CPT 76999** with guidance provided to providers and patients

## Clinical Use Cases

- Safe breast imaging option for patients 18 years of age or older
- Imaging alternative for patients unable to tolerate MRI (e.g., claustrophobia and contrast allergies)
- Supplemental imaging for women with dense breasts
- Adjunct follow-up imaging for inconclusive or suspicious mammogram findings
- Ongoing monitoring of benign lesions (e.g., cysts, fibroadenomas) without radiation exposure
- Ongoing monitoring of lesion doubling time to assess growth dynamics

## Commercial Momentum and Revenue Growth

- The company continues to demonstrate rapid commercial traction; Q3 2025 revenue reached \$4.2M, representing 15% sequential growth
- Nine scanners were shipped in Q3 along with five additional shipments in October for a total of 28 scanners shipped year to date
- Advanced global expansion with Gulf Medical as new strategic distribution partner in Saudi Arabia
- Contracted revenue includes \$18M for 2025 and \$39M for 2026 driven by minimum order quantities from NXC Imaging in the USA and Gulf Medical in Saudi Arabia
- Applied to relist on NASDAQ less than nine months after leaving the exchange
- Appointed senior leadership: Satrajit Misra as Chief Commercial Officer and Jay Jennings as Chief Financial Officer

## Investment Highlights

- **Industry transforming FDA-cleared breast imaging platform** with Breakthrough Device Designation
- Large addressable markets including a \$6B + breast imaging market and a \$1B biomarker and SaaS opportunity
- **True 3D, quantitative, high resolution breast imaging with no discomfort or contrast as MRI**
- **Higher specificity and improved non cancer recall rates** compared to traditional mammography under a favorable safety profile
- **Quantitative imaging** foundation ideal for artificial intelligence and precision medicine
- **Strong commercial momentum with \$57M contracted revenue** in 2025 and 2026
- **Scalable distribution** partnerships with NXC Imaging in USA and Gulf Medical in Saudi Arabia
- **Mature regulatory pipeline** in the USA, Saudi Arabia, and Europe

<sup>1)</sup> Coherent Market Insights

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