

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

**CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934**

Date of Report (Date of earliest event reported): April 1, 2024

QT Imaging Holdings, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or other jurisdiction
of incorporation)

001-40839
(Commission
File Number)

86-1728920
(IRS Employer
Identification No.)

**3 Hamilton Landing, Suite 160
Novato, CA 94949**
(Address of principal executive offices)

(650) 276-7040
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbols	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	QTI	The Nasdaq Stock Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01 Regulation FD Disclosure

On April 1, 2024, QT Imaging Holdings, Inc. (the “Company”) posted to the Company’s Investor Presentations section of its website www.qtimaging.com, an investor presentation containing supplemental product and operational information regarding the Company. A copy of the investor presentation is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in, or incorporated into, this Item 7.01 of this Report, including Exhibit 99.1 attached hereto, is furnished under Item 7.01 of Form 8-K and shall not be deemed “filed” for the purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference into the filings of the Company under the Securities Act or the Exchange Act regardless of any general incorporation language in such filings.

This Report shall not be deemed an admission as to the materiality of any information in this Report that is being disclosed pursuant to Regulation FD.

Please refer to Exhibit 99.1 for a discussion of certain forward-looking statements included therein and the risks and uncertainties related thereto.

Item 9.01 Financial Statements and Exhibits.

The exhibits required by this item are set forth on the Exhibit Index attached hereto.

**Exhibit
Number**

99.1 [Investor Presentation dated April 2024.](#)

104 Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: April 1, 2024

By: /s/ Dr. Raluca Dinu
Name: Dr. Raluca Dinu
Title: Chief Executive Officer



Quantitative Transmission Imaging

Breast Acoustic CT™ Scanner

INVESTOR
PRESENTATION
April 2024



Disclaimer

ABOUT THIS PRESENTATION

This investor presentation (this "Presentation") is provided for informational purposes only. The information contained herein does not purport to be all-inclusive and neither QT Imaging Holdings, Inc. (the "Company", "QT Imaging Holdings", "QTI"), nor its respective directors, officers, employees, agents, advisors or affiliates, including QT Imaging, Inc. ("QT Imaging"), makes any representation or warranty, express or implied, as to the accuracy, completeness or reliability of the information contained in this Presentation, which has not been verified and is subject to change at any time. Viewers of this Presentation should each make their own evaluation of QT Imaging Holdings and of the relevance and accuracy of the information and should make such other investigations as they deem necessary. To the fullest extent permitted by law, no responsibility or liability whatsoever is accepted by QT Imaging Holdings, or its directors, officers, employees, agents, advisors or affiliates for any loss howsoever arising, directly or indirectly, from any use of this Presentation or such information or opinions contained herein or otherwise arising in connection herewith.

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On June 6, 2017, the U.S. Food and Drug Administration ("FDA") in response to QT Imaging's Section 510(k) Summary of Safety and Effectiveness premarket notification under the Food, Drug and Cosmetic Act, determined that the QT Breast Scanner is substantially equivalent to the predicate device. Our use of the words "safe", "safety", "effectiveness", and "efficacy" in relation to the QT Breast Scanner in this Presentation and all other QT Imaging related documents is limited to the context of the Section 510(k) Summary of Safety and Effectiveness that was reviewed and responded to by the FDA.

TRADEMARKS AND INTELLECTUAL PROPERTY

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Disclaimer

FORWARD LOOKING STATEMENTS

Certain statements included in this Presentation that are not historical facts are forward-looking statements for purposes of the safe harbor provisions under the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements generally are accompanied by words such as "has the potential to", "believe", "may", "will", "estimate", "continue", "anticipate", "intend", "expect", "should", "would", "plan", "predict", "potential", "seem", "seek", "future", "outlook", and similar expressions that indicate or predict future events or trends that are not statements of historical matters. These forward looking statements include, but are not limited to, the potential impact on existing medical technology, the company's technology, products, business prospects, revenue, client adoptions, commercialization, projections of market opportunity and statements regarding estimates and forecasts of other financial and performance metrics. These statements are based on various assumptions, whether or not identified in this Presentation, and on the current expectations of QT Imaging Holdings' management and are not predictions of actual performance. These forward-looking statements are provided for illustrative purposes only and are not circumstances intended to serve as, and must not be relied on by any investor as, a guarantee, an assurance, a prediction or a definitive statement of fact or probability. In addition, statements regarding the Company's products, technology, and market opportunity reflect the beliefs and opinions of QT Imaging Holdings' management on the relevant subject as of this Presentation. Actual events and circumstances are difficult or impossible to predict and will differ from assumptions. Many actual events and circumstances are beyond the control of QT Imaging Holdings. These forward-looking statements are subject to a number of risks and uncertainties, including changes in domestic and foreign business, market, financial, political and legal conditions; risks related to the rollout of QT Imaging Holdings' business and the timing of expected business milestones; the demand for QT Imaging Holdings' products and services; the ability of QT Imaging Holdings to increase sales of its output products in accordance with its plans; issues that could arise during the course of the acquisition of QT scanners by CMSC or the Feasibility Study; the desire of customers and service recipients to continue engaging QT Imaging Holdings; the effects of competition on QT Imaging Holdings' future business, changes in the Company's strategy, future operations, financial positions, and product development timeline. If any of these risks materialize or our assumptions prove incorrect, actual results could differ materially from the results implied by these forward-looking statements. There may be additional risks that QT Imaging Holdings presently does not know or believes is immaterial that could also cause actual results to differ from those contained in the forward-looking statements. In addition, forward-looking statements reflect QT Imaging Holdings' expectations, plans or forecasts of future events and views as of the date of this Presentation. QT Imaging Holdings anticipates that subsequent events and developments will cause its assessments to change. However, while QT Imaging Holdings may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing QT Imaging Holdings' assessments as of any date subsequent to the date of this Presentation. Accordingly, undue reliance should not be placed upon the forward-looking statements.



QT Imaging Holdings (QTI) Has the Potential to Transform Medical Imaging

- QTI is a medical device company with imaging technology that has the **potential to transform the industry**
- QTI Scanner is **the only 3D imaging device to receive FDA clearance** for use as a transmission and reflection ultrasonic imaging system of a patient's breast
- QTI's patent-protected technology provides a relatively low-cost, comprehensive, no radiation, no discomfort medical imaging solution
- QTI's technology **yields superior performance compared to traditional mammogram** with regard to specificity (false positives) and has **similar imaging quality and diagnostic value compared to MRI** but is a lower cost and **more accessible solution.**



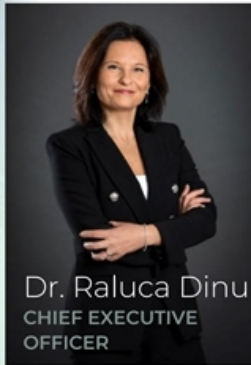
QT Imaging Holdings (QTI) Has the Potential to Transform Medical Imaging

- This sub-millimeter, high-definition, image resolution enables the **identification of normal and abnormal breast structures** and the accurate depiction and measurement of the precise shape and location of findings, as well as being suitable for **full body imaging and other applications**

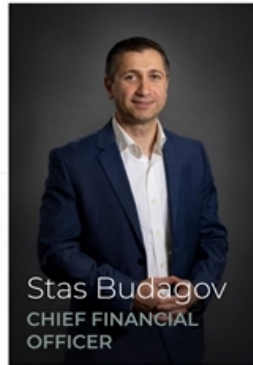


- QTI was founded by John Klock, MD, who is recognized globally as a **successful co-founder of multiple companies**, including one that successfully commercialized five FDA-approved drugs
- A **commercialization experienced executive team** joined QTI to drive market penetration

Introduction to the QT Imaging Holdings Management Team



Dr. Raluca Dinu is a global business executive, with long public companies' governance experience, offering over 22 years of achievements in the high-tech industry, with an established track record of driving increased revenue and profitability, delivering strong results in turnaround or M&A situations, leading strategic growth, and consolidation in fast-paced business environments.



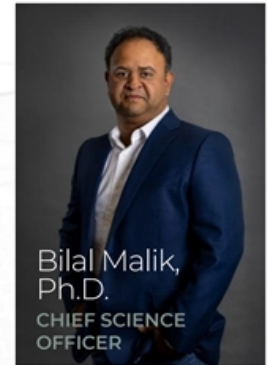
Mr. Budagov is serving as CFO of QTI since December 2023. He has more than 15 years of accounting and consulting experience, including consulting public and private clients. Additionally, he has 3 years of audit experience at Ernst & Young.



Mr. Steve Choate, appointed as Chief Operations Officer at QTI in April 2024, is responsible for managing the operations organization, ensuring quality, and fostering collaboration with internal, domestic, and international manufacturing partners.



Mr. Pirshafiey has been with QTI since 2017. Previously, he founded and managed a consulting firm providing sustainable practices to industries including medical device, high-tech, and consumer products for giants such as Johnson & Johnson and Siemens. He has 14 inventions filed with the US patent office.



Dr. Bilal Malik has over ten years of experience in research, development, and translation of medical devices, both in academia and industry. He is an expert in leading and directing efforts in image and data science and has a track record of successfully leading innovation for medical imaging products.



Our Mission

- **Create disruptive innovation**—a dedication to using technology (software, artificial intelligence, and smart physics) to improve medical imaging and thus **health care quality and access**.
- Continue to improve **our FDA-cleared, high quality, high resolution, native 3D, reproducible image quality regardless of operator or breast size/tissue type breast imaging technology**, as well as the techniques for quantifiable analysis, comparison, and training.
- Introduce the **first comprehensive body-safe imaging technology** into the marketplace, enabling for the first-time **well-person body imaging** health screening, and the first health screening **medical imaging for infants**.
- Expand the market opportunities beyond hospitals, imaging centers and health centers **by supporting additional direct to consumer (DTC) and direct to provider (DTP) approaches to enable the ability to lower health care costs** and increase access via personal medical imaging.
- Improve medical outcomes globally by **increasing access** to medical imaging.

NIH has awarded
QT Imaging about
\$18M
for new women's
imaging solution



National Institutes
of Health



Executive Summary

- **Low-cost, comprehensive, quantitative, no radiation medical imaging solution** yielding sub-millimeter, high-definition, image resolution: application in areas such as **breast • infant body • full body**
- Commercial stage, FDA-cleared⁽¹⁾ breast scanner **for dense breast imaging**, with better sensitivity and specificity than mammography and potential for:
 - Applicability to determine **a measure of** breast density and measure mass size and growth
 - Improved compliance with screening guidelines
 - Expanded FDA clearances to increase access to medical imaging in multiple applications, including preventative screening
- **Breakthrough Device Designation awarded by the FDA** provides fast track to unique CPT codes and future clearances
- Patent-protected technology: **14 granted US/Europe**
 - Software platform protected by trade secrets
- **Sales Agent Agreement signed with NXC Imaging (A Subsidiary of Canon Medical Systems)**
- **Feasibility Study Agreement signed with Canon Medical Systems**
- Go-to-market strategy:
 - US: Distributor network with strategic partners
- Developed roadmap for additional FDA clearances, product development, clinical adoption, and commercialization

(1) FDA Labels: K162372, K181785, K190626, KD22093, Q181785

QTI's Technology Has the Opportunity to Transform Several Large Markets

2022 GLOBAL MEDICAL IMAGING MARKET SIZE: \$29B⁽¹⁾

Current Market

BREAST: \$5B MARKET⁽²⁾

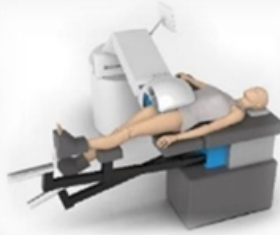
- FDA approved as supplementary screening device for breast imaging
- Aim to revolutionize current imaging paradigm, replacing mammography, ultrasound (handheld and automated), and freeing MRI scanners time



Future Markets – Body Scanner Platform Development

ORTHO: \$9B MARKET⁽³⁾

- Target replacing MRI examinations
- Primary focus on orthopedic practices



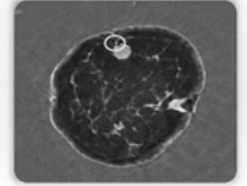
INFANT: \$8B MARKET⁽⁴⁾

- New market opportunity given limitations of current imaging modalities for infants



IMAGE-GUIDED PROCEDURES: \$5B MARKET⁽⁵⁾

- Commenced feasibility study
- Variety of image-guided procedures including biopsies, injections and cryoablation



Agreement Signed with NXC Imaging A Subsidiary of Canon Medical Systems

- Sales Agent Agreement signed with NXC Imaging marks a major milestone for QTI
- Accessing NXC Imaging's distribution channel in the US and the US territories, **this agreement provides potential to accelerate the commercial roll-out of QTI's imaging systems**
- NXC Imaging will also provide a mature service organization to support QTI's installed base



Feasibility Study Agreement Signed with Canon Medical Systems

- Canon to **initiate studies to evaluate the business, technical, and clinical values of QTI's ultrasound breast scanner** including:
 - product quality validation
 - development and manufacturing studies
 - clinical evaluation
 - regulatory investigation, and
 - market validation.
- QTI shall provide support for the feasibility study with Canon and shall use its commercially reasonable efforts to facilitate the feasibility study.
- **All know-how and intellectual property embodied in the QT Scanner are owned by QTI.**
- During the term of the Feasibility Study Agreement, the **QTI shall give Canon first priority in any negotiations for collaborations, including joint development, contract manufacturing, and marketing, with respect to ultrasound breast scanners.**

The Canon logo is displayed in its characteristic red, bold, sans-serif font.



QT IMAGING

TECHNOLOGY
OVERVIEW



Current Ultrasound Technologies Have Major Deficiencies

Shortfalls of Commercial Current, Rival Systems⁽²⁾:

- **Reflection images have speckle; compounding without refraction correction**
- No valid true "transmission" mode – use "shear wave" (**low resolution**) data (ABUS, AVUS, etc. are not transmission)
- Data yielded is **compounded 2D – not true "3D"** - Transmission images have artifacts.
- Low contrast-to-noise ratios (speckle)
- **Specificity for masses is relatively poor**
- Unable to view consistently calcifications – **misses 20% of cancers⁽¹⁾**
- **No "functional" imaging** features for most (doubling time, tissue identification and specific tissue volume segmentations)
- **Poor reproducibility** of measurement and volume data
- Operator dependence (HHUS)

⁽¹⁾ A Multireader Multicase (MRMC) Receiver Operating Characteristic (ROC) Study Evaluating Noninferiority of Quantitative Transmission (QT) Ultrasound to Digital Breast Tomosynthesis (DBT) on Detection and Recall of Breast Lesions
Jiang, Yulei et al., Academic Radiology, in press.

⁽²⁾ Based on opinion of QT management. QT believes necessary data has been obtained through 18 separate clinical trials



Critical Modality Advantages of QTI's Breast Acoustic CT⁽¹⁾

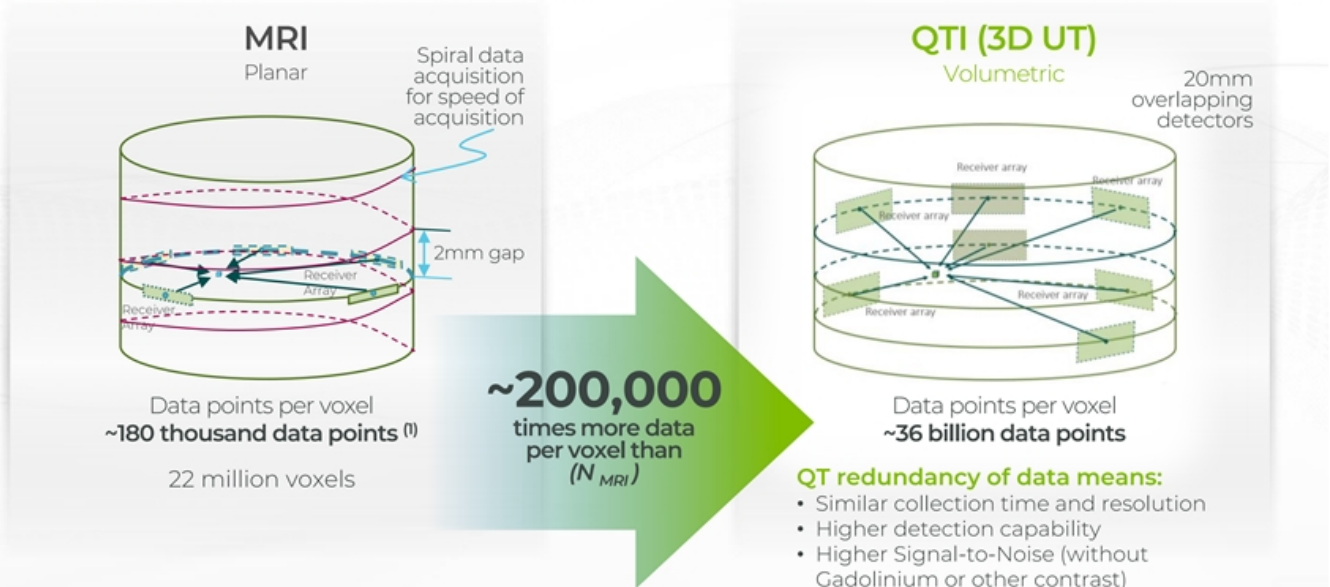
- Clinically useful **sensitivity and specificity**
- Presence of **comparative clinical trials**
- Proven success in head-to-head trials against mammography **for primary screening**
- Ability to determine doubling times – can identify slow growing cancers and help **prevent cancer deaths**
- **Enhanced volume measurements** – can follow cancer treatments and provide breast density measurements
- Patented technology opens the door for potential **future growth in orthopedic and pediatric imaging**



(1) Based on opinion of QTI Imaging. QTI believes necessary data has been obtained through 18 separate clinical trials

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Why QTI Scan Generates Better Resolution Compared to MRI: **More Data!**



(1) Y. Gao and S. L. Heller, "Abbreviated and Ultrafast Breast MRI in Clinical Practice," RadioGraphics, vol. 40, pp. 1507-1527, 2020

Note: Voxel is a 3D version of a pixel

Market Positioning of Breast Acoustic CT Scanner

Not intended to compete with mammography for screening, **although many patients may find it preferable for:**

- Dense breasts
- Implants
- Post therapy screening where breasts can be very sensitive to compression
- When concerned about radiation dose

Diagnostic alternative to MRI

- Lower cost, faster, more accessible
- Similar image quality and diagnostic value
- More tolerable for patient (claustrophobia, noise, time, no contrast)
- Images are inherently quantitative and repeatable, and hence serve as an imaging biomarker (helps following a patient)
- Scanner is easily deployable (<2 days) and frees MRI scanners for other non-breast imaging studies

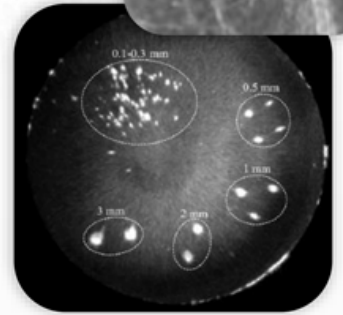
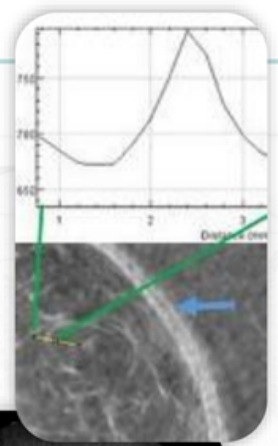
Diagnostic alternative to Hand-held Ultrasound

- Native 3D imaging (like MRI and CT)
- Quantifiable image analysis
- No need for specialized technologist training
- Consistent and reproducible image quality regardless of operator



Technical Capabilities

- **Resolution of ~600 microns in reflection** compared to 800 microns⁽¹⁾ for MRI (depends on field strength, homogeneity etc)
- **Contrast to noise ratio of 23:1 at 100 microns** (in reflection; can detect small calcifications)
- **Contrast to noise ratio of 15:1** (at resolution in transmission – speed of sound)
- **Speckle-free because of 360° compounding and refraction correction** for reflection image
- **Volumetric data acquisition (3D)**, not stacked 2D slices
- Volumetric reproducibility 0.2% for fibro glandular volume
- Volumetric accuracy better than 3% extrapolated from linear accuracy ~1% (vertical < 2%)



(1) Y. Gao and S. L. Heller, "Abbreviated and Ultrafast Breast MRI in Clinical Practice," RadioGraphics, vol. 40, pp. 1507-1527, 2020

Enhanced Clinical Capabilities and Value

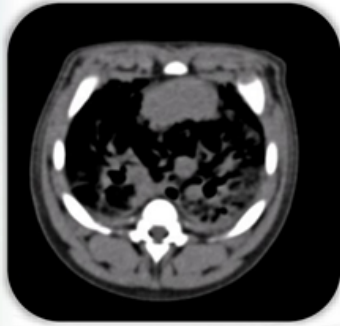
- **High-quality and high-resolution native 3D Imaging**
- **Quantifiable images** enables accurate analysis, comparison and trending
- Consistent and reproducible image quality **regardless of operator or breast size/tissue type.**
- **Clinical feature detection of 50-100 microns** including microcalcifications
- Functional imaging capability - **determine tissue type from the speed of sound**
- **Allows tissue doubling time assessments – similar to MRI and CT**
- Highly accurate measurements, **not scanner operator dependent**

(1) Y. Gao and S. L. Heller, "Abbreviated and Ultrafast Breast MRI in Clinical Practice," RadioGraphics, vol. 40, pp. 1507-1527, 2020

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Resolution and Detectability: MRI vs QTI's Acoustic CT (3D UT)

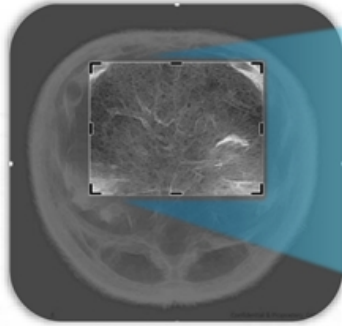
MRI



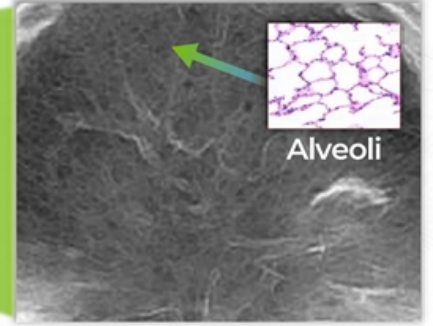
MRI
image of
a piglet
lung

MRI resolution depends on acquisition time, B1 inhomogeneity, etc.

QTI's Acoustic CT



Higher resolution than 3T MRI in air-filled organs

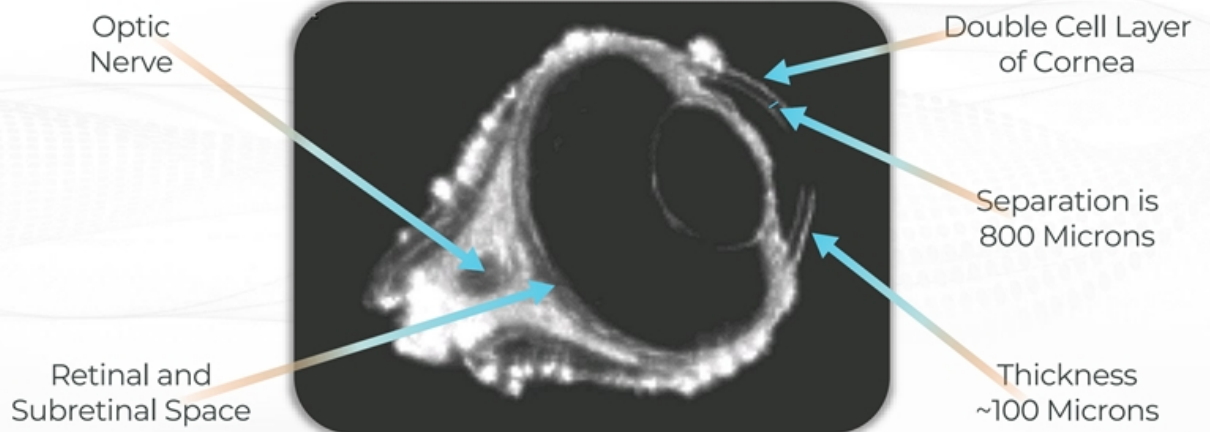


QTI's Acoustic CT (3D UT) with reflection mode

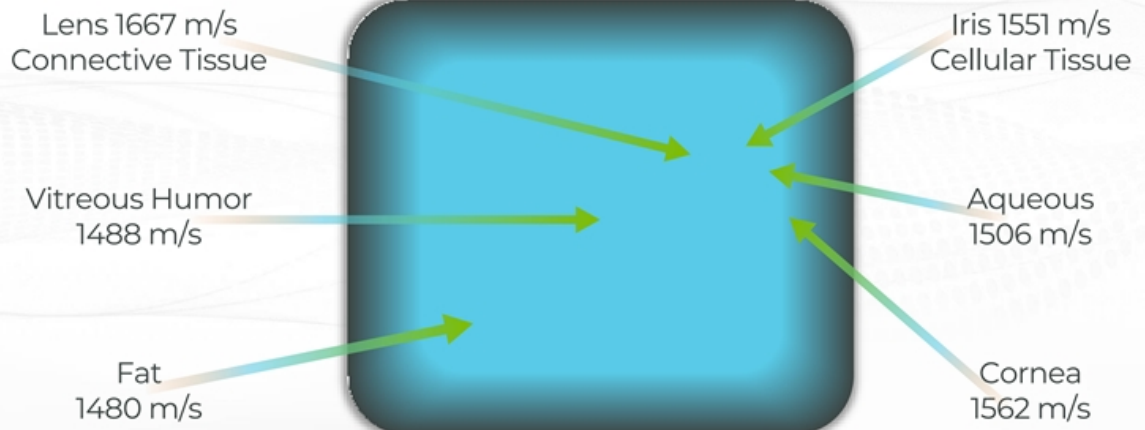
- Resolution is almost isotropic (transmission)
- Sub-mm resolution
- Detectability 0.1 mm

First time structures as small as the Lung Alveoli can be seen in vivo!

Bovine Eye: Reflection, ex vivo



Bovine Eye: Speed of Sound, ex vivo





QT IMAGING

BREAST HEALTH



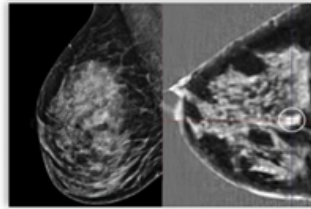
QT Imaging's FDA-cleared Solution for Dense Breasts

Many Women Have Dense Breasts, Which Mammograms are Inefficient in Screening for Cancer



50% of women between the ages of 40-74 in the US have dense breasts⁽¹⁾

In ~84% of cases observed in a recent mini-study, QT Scanner identified abnormalities in dense breasts that were not identified by x-ray mammograms⁽²⁾



X-Ray Mammogram QT Scan

The FDA Has Recognized the Importance of Breast Density in Breast Cancer Screening

Mammograms Must Include Breast Density Information, New FDA Rule Says

About half of the women over the age of 40 in the U.S. have dense breast tissue, which can make cancer scans hard to read⁽³⁾



"the new rule advises physicians and patients to consider breast density alongside other cancer risk factors when deciding whether additional screening is necessary"

– Hilary Marston,
CHIEF MEDICAL OFFICER, FDA

Mammography Misses 35.6–52.2% of Breast Cancers in Dense Breast Tissue⁽⁴⁾

(1) Breast Density on a Mammogram, Susan G. Komen

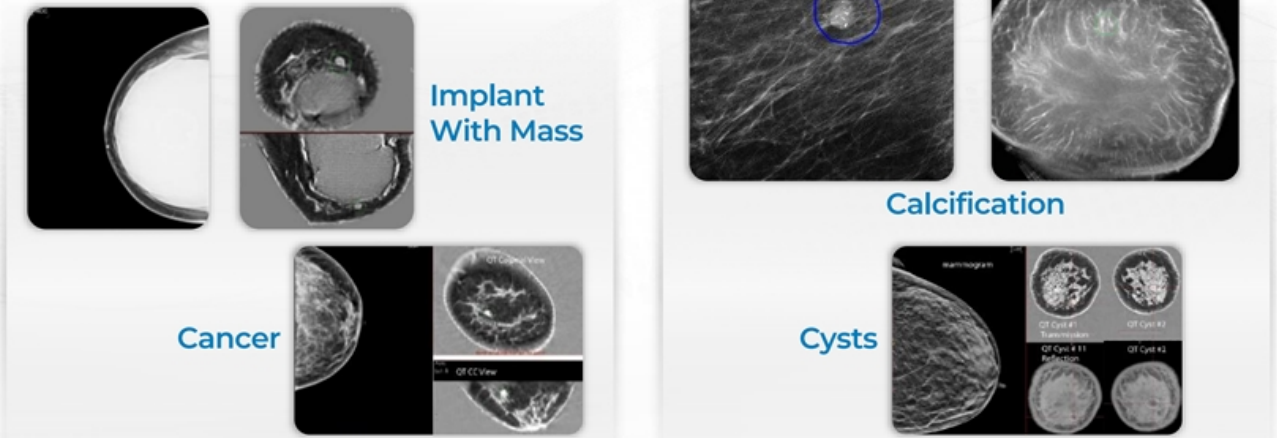
(2) QT1 Study | Dense Breast Mass Detection

(3) "Mammograms Must Include Breast Density Information, New FDA Rule Says", Wall Street Journal

(4) The Role of Ultrasound in Screening Dense Breasts. NCBI.

CLINICAL TRIALS: Dense Breast Imaging Studies Using DBT Show Sensitivity Close to 40%⁽³⁾

Approximately 50% of women between the ages of 40-74 in the US have dense breasts⁽¹⁾, with traditional mammography missing 35.6-52.2% of breast cancers in dense breast tissue⁽²⁾ making QT Scanner the only system effective at screening dense breast.



QTI can see calcification missed by other imaging systems and is particularly effective in imaging dense breasts







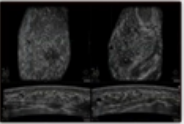
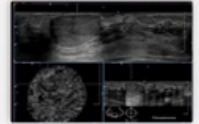
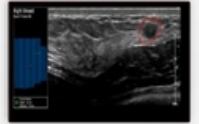

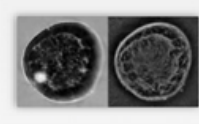
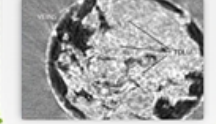
[1] Breast Density on a Mammogram, Susan G. Komen

[2] The Role of Ultrasound in Screening Dense Breasts. NCBI.

[3] C. E. Comstock, MD, C. Gatsonis, PhD et al. "Comparison of Abbreviated Breast MRI vs Digital Breast Tomosynthesis for Breast Cancer Detection Among Women With Dense Breasts Undergoing Screening", JAMA 2020, 323(8):746-756

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Other Ultrasound Products Use 2D Imaging for Dense Breast Screening

GE Healthcare	SIEMENS	SonoCine	HITACHI	Delphinus Medical Technologies	QT IMAGING
INVENIA ABUS	ACUSON S2000 ABVS	AWBUS	SOFIA 3D	DELPHINUS SOFTVUE	BREAST ACOUSTIC CT
					
DESIGN TYPE					
Articulating Arm	Articulating Arm	Articulating Arm Guided Handheld	Rotating Armature	Water Bath	Water Bath
OUTPUT					
Stacked 2D Reflection Slices	Stacked 2D Reflection Slices	Stacked 2D Reflection Slices	Stacked 2D Reflection Slices	Stacked 2D Slices	Only Full 3D
					

Mammography is ineffective in screening dense breasts.
 Ultrasound techniques performed after MRI did not detect additional cancer⁽¹⁾ in dense breast



(1) Integration of Handheld Ultrasound or Automated Breast Ultrasound among Women with Negative Mammographic Screening Findings: A Multi-center Population-based Study in China
 Source: Manufacturer's websites
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The Current Breast Imaging Paradigm Leads to Unnecessary Concern and Costs

Screening compliance is low



Of the **65%** of women who do get screened, many suffer through unnecessary callbacks

Aside from the discomfort of the mammogram procedure, **up to 15% of women are called back** for additional procedures such as ultrasound, MRI or biopsies – which can be **expensive, time consuming and cause significant anxiety**⁽²⁾

For every **1,000** screening mammograms:

CALL BACK RATES
~15% call-backs rates with mammography

150



98% of Recalls are Avoidable

BIOPSIES
~10% biopsy rate for callbacks

15



Over 80% of Callback Biopsies are Benign⁽⁴⁾

CANCER INCIDENCE
0.3% cancer diagnosis⁽⁵⁾

3



Current and Future Uses of QT Breast Scanner

The QT Breast Scanner has been granted FDA clearances that allow for meaningful clinical use, with potential for a future roadmap to provide a replacement to screening mammography, a transformational milestone that would significantly expand the market opportunity

CURRENT APPLICATION

- Currently used in clinics for supplementary screening and diagnostic imaging. It cannot be marketed as a replacement for the mammogram at this time.

- **FDA clearances in place:**

- Breast Imaging (K162372)
- Software Improvements (K181785, K190626)
- Breakthrough Device Designation (Q181785)
- Measure Fibroglandular Volume (K220993)

"The QT Ultrasound Breast Scanner – 1 is for use as an ultrasonic imaging system to provide reflection-mode and transmission-mode images of a patient's breast. The device is not intended to be used as a replacement for screening mammography."

- Food and Drug Administration
510(k) Premarket Notification of Intent K162372

"The QT Scanner 2000 Model A is for use as an ultrasonic imaging system to provide reflection mode and transmission-mode images of a patient's breast. The QT Scanner 2000 Model A software also calculates the breast fibroglandular tissue volume (FGV) value and the ratio of FGV to total breast volume (TBV) value as determined from reflection-mode and transmission mode ultrasound images of a patient's breast. The device is not intended to be used as a replacement for screening mammography.

The QT Scanner 2000 Model A is indicated for use by trained healthcare professionals in environments where healthcare is provided to enable breast imaging in adult patients."

- Food and Drug Administration

(f) FDA | 510(k) Premarket Notification of Intent K220933

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Current and Future Uses of QT Breast Scanner

The QT Breast Scanner has been granted FDA clearances that allow for meaningful clinical use, with potential for a future roadmap to provide a replacement to screening mammography, a transformational milestone that would significantly expand the market opportunity

FUTURE POTENTIAL APPLICATIONS

NEAR-TERM:

- Use applicability for **determining breast density, measuring mass size and growth, and diagnosing lesions using** artificial intelligence to expand into supplementary imaging market

MEDIUM-TERM:

- FDA has granted QT Scanner a **Breakthrough Device Designation for screening younger and High-Risk women**
- **Screening for High-Risk (Family History and Genes) Young Women:** providing at-risk young women a safe, comfortable, and accurate method to screen for breast cancer

LONG-TERM (MAJOR MILESTONE):

- **Alternative to Screening Mammography:** our goal is to provide all women a safe, comfortable, and accurate method to screen for breast cancer

(1) FDA | 510(k) Premarket Notification of Intent K220933

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QTI Offers Potential Capabilities for Screening, Diagnosis, and Monitoring



SUPPLEMENTAL SCREENING

- Supplementary screening (Approved)
 - Dense Breasts
 - Intermediate to high-risk women
 - Implants
- Primary screening for mammogram underserved patients (age <35)
 - Young, high-risk women with predisposal to cancer or previous chest radiation
 - Any woman who believes they are at risk
- Adjunctive and/or alternative to handheld ultrasound
- Alternative to breast MRI with gadolinium injection



DIAGNOSIS

- Quantification of fibroglandular volume (Approved)
- AI-enabled diagnostics
- Accurate tumor size
- Potential for biopsy procedures with the 2nd generation open angle scanner (currently under development)
- Can accurately determine growth rate of tumors, thus identifying aggressive cancers

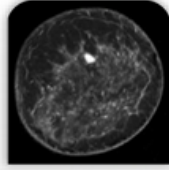


MONITORING

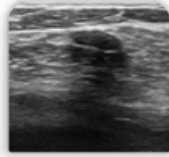
- Ability to safely use repeatedly – no side effects/ non-invasive
- Measure and track mass size and growth
- Assess response to treatments

QTI imaging technique has the capability to replace MRI for dense breasts (no injection, no discomfort)

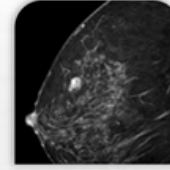
The QT Scanner Delivers a Better Experience for Patients than Traditional Systems



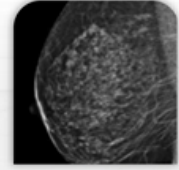
QT IMAGING



HANDHELD ULTRASOUND



MRI



MAMMOGRAPHY

Image Quality



Safety⁽¹⁾



Speed



Cost Efficiency



Patient Experience



The QTI Imaging Advantage

...OVER HHUS

- Superior image quality
- Not operator dependent
- Quantifiable/repeatable

...OVER MRI

- High resolution and contrast-to-noise ratio
- No injection needed
- Lower equipment cost
- No special facility or shielding requirements

...OVER MAMMOGRAPHY

- Improved image quality
- Safer (no radiation), allowing for more frequent imaging
- Greater sensitivity and specificity
- No special facility requirements
- Quantifiable/repeatable



(1) No radiation exposure or injections necessary

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QTI Clinical Trials Provide Compelling Results for Adoption and Approvals

CLINICAL TRIALS

- Visual Grading Assessment of Quantitative Transmission Ultrasound Compared to Digital X-ray Mammography and Hand-held Ultrasound
- Anatomy-Correlated Breast Imaging and Visual Grading Analysis Using Quantitative Transmission Ultrasound
- Accuracy of Cyst vs. Solid Diagnosis in the Breast Using Quantitative Transmission (QT) Ultrasound
- Breast Cyst Fluid Analysis Correlations Using Transmission Ultrasound
- Objective Breast Tissue Image Classification Using Quantitative Transmission Ultrasound Tomography
- Quantitative Assessment of Breast Density: Transmission Ultrasound is Comparable to Mammography with Tomosynthesis
- An Exploratory Study Comparing Transmission Ultrasound to Mammography on Recall Rates and Detection Rates for Breast Cancer
- QT Ultrasound Tomography for Orthopedic Imaging
- QT Ultrasound for Whole Body Imaging

IMPLICATION OF RESULTS OR PRELIMINARY RESULTS

QT can **see more anatomy** than mammography or handheld ultrasound

QT can **distinguish specific tissues** unlike mammography or handheld ultrasound

QT can **quantify breast density** unlike mammography or handheld ultrasound

QT can **identify breast and reduce recall rates** better than mammography

QT **can identify bone and joint structures**

QT **can identify internal body structures**



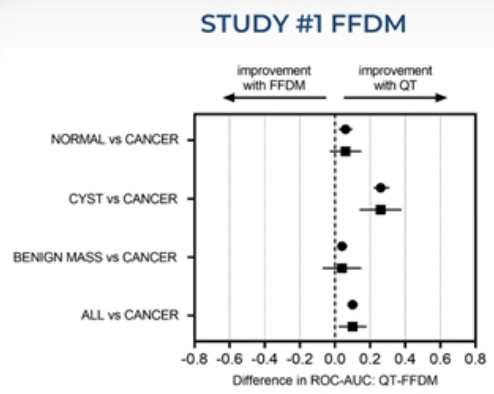
Dr. Susan Love Fund for Breast Cancer Research

Canada's premier Cancer centre:

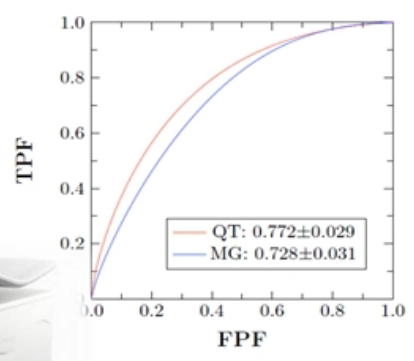


Two Clinical Trials Completed and Published

QT Performance Relative To FFDM and DBT in Mass Detection



STUDY #2 (Comparison to Digital Breast Tomosynthesis)



In recent studies, QT outperformed today's gold standard (Digital Breast Tomosynthesis)



[1] Study #1: An Exploratory Multi-reader, Multi-case Study Comparing Transmission Ultrasound to Mammography on Recall Rates and Detection Rates for Breast Cancer Lesions
 [2] A Multireader Multicase (MDMC) Receiver Operating Characteristic (ROC) Study Evaluating Noninferiority of Quantitative Transmission (QT) Ultrasound to Digital Breast Tomosynthesis (DBT) on Detection and Recall of Breast Lesions
 Jiang, Yulei et al., Academic Radiology, in press.



QT IMAGING

CLINICAL
ADOPTION



Key Milestones Have Been Achieved With Additional Catalysts to Drive Commercial Adoption and Increased Market Share

Breast Acoustic CT™ System ▶ 18 months

Key Milestones Achieved for Commercial Adoption

- ✓ Four placements in North America to date and more on the way
- ✓ Signed Sales Agent Agreement with NXC Imaging (A Subsidiary of Canon Medical Systems) for worldwide sales and service rollout
- ✓ Signed Feasibility Study Agreement with Canon Medical Systems



Catalysts for Further Commercial Adoption

- Screening adjunct clearance for high-risk young women
- Primary screening clearance for all women subject to FDA approval
- Product enhancements while further developing sales and marketing team

▶ FDA Clearance for Primary Screening

Millions of young, at-risk women can benefit from QTI's potential FDA clearance for primary screening



Reimbursement Will Be Driven by the Value and Savings Provided to Patients

EXISTING

- CPT codes, non-specific to QTI technology:
 - Unilateral or Bilateral breast ultrasound (76641 or 76642)
 - 3D rendering (76377)
 - Other ultrasound procedures (76999)



FUTURE

- CPT code specific to QT Scanner®
 - Higher reimbursements capture full value of unique advantages that QT Scans offer
 - Process to QTI-specific code facilitated by breakthrough designation
- Reimbursement agreements with specific insurance companies and programs
 - Integrated health systems focused on minimizing overall cost of care
 - Programs serving higher risk groups



QT IMAGING

OPEN ANGLE
SCANNER

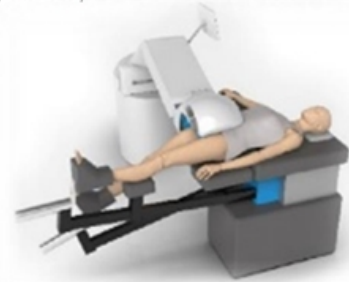


Developing an Open Angle Scanner Will Expand the Technology to New Markets

Development of the open angle scanner is underway...

- QTI has successfully completed feasibility studies for partial angle reconstruction
- QTI has verified the ability to perform data acquisition and image reconstruction with a membrane within the field
- Working to design a platform that accommodates orthopedic, infant, other individual organs, and full body imaging

The Open Angle Scanner has the potential to offer a safe and affordable in-office imaging solution



Developing an Open Angle Scanner Will Expand the Technology to New Markets

...providing significant potential to access new markets and applications

- The Open Angle Scanner uses an open, partial angle configuration which reduces the viewing field from 3600 to 3250 and provides additional capabilities for QTI technology in:
 - Orthopedic imaging
 - Other organs (as prostate)
 - Whole body infant scanning
 - Biopsy and image-guided diagnostic and treatment procedures
- The scanner satisfies the need for better image reconstruction techniques in partial-ring tomography systems
- Potential to prevent cancers from developing into advanced stages
- Representative point-of-care target markets include:

ORTHOPEDIC
SURGEONS
[IN-OFFICE]



SPORTS
TEAMS
[ON THE
FIELD]



MILITARY
[SHIPS &
FIELD USE]



The Infrastructure is in Place to Allow for the Rollout of the Next Generation Scanner

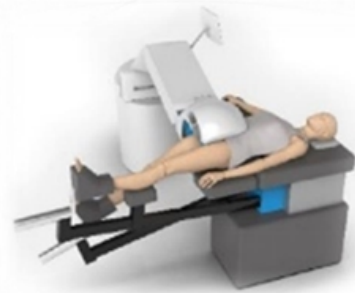
Next Generation Open Angle Scanner

Key Infrastructure in Place for Development

- ✓ Underlying ultra-low frequency sound emitting technology
- ✓ Initial Proof of Concept
- ✓ Commencement of prototype design and build

Upcoming Catalysts for Rollout

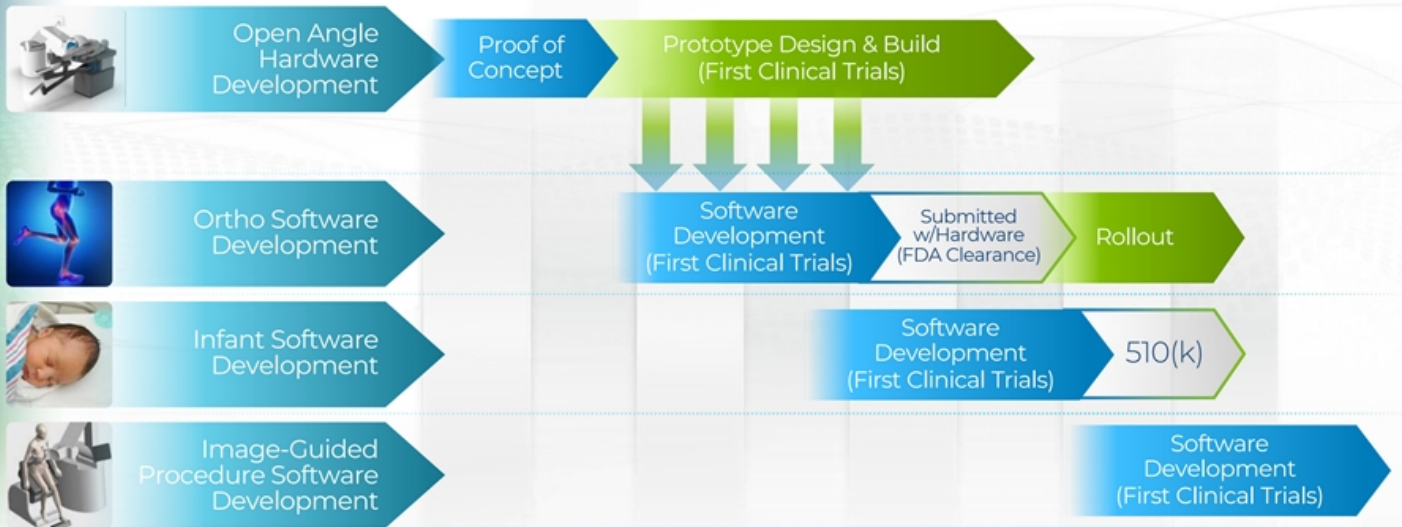
- Software development
- FDA approvals



Prototype Design and Build

Next generation open angle scanner will allow QTI to access adjacent areas such as ortho, infant, and image guided procedures

Open Angle Scanner Development Pathway and Corresponding Catalysts



Investment Highlights

Cutting-edge imaging technology with multiple potential applications creates a tremendous opportunity to transform the imaging market



(1) Coherent Market Insights



QT IMAGING

Thank You!

