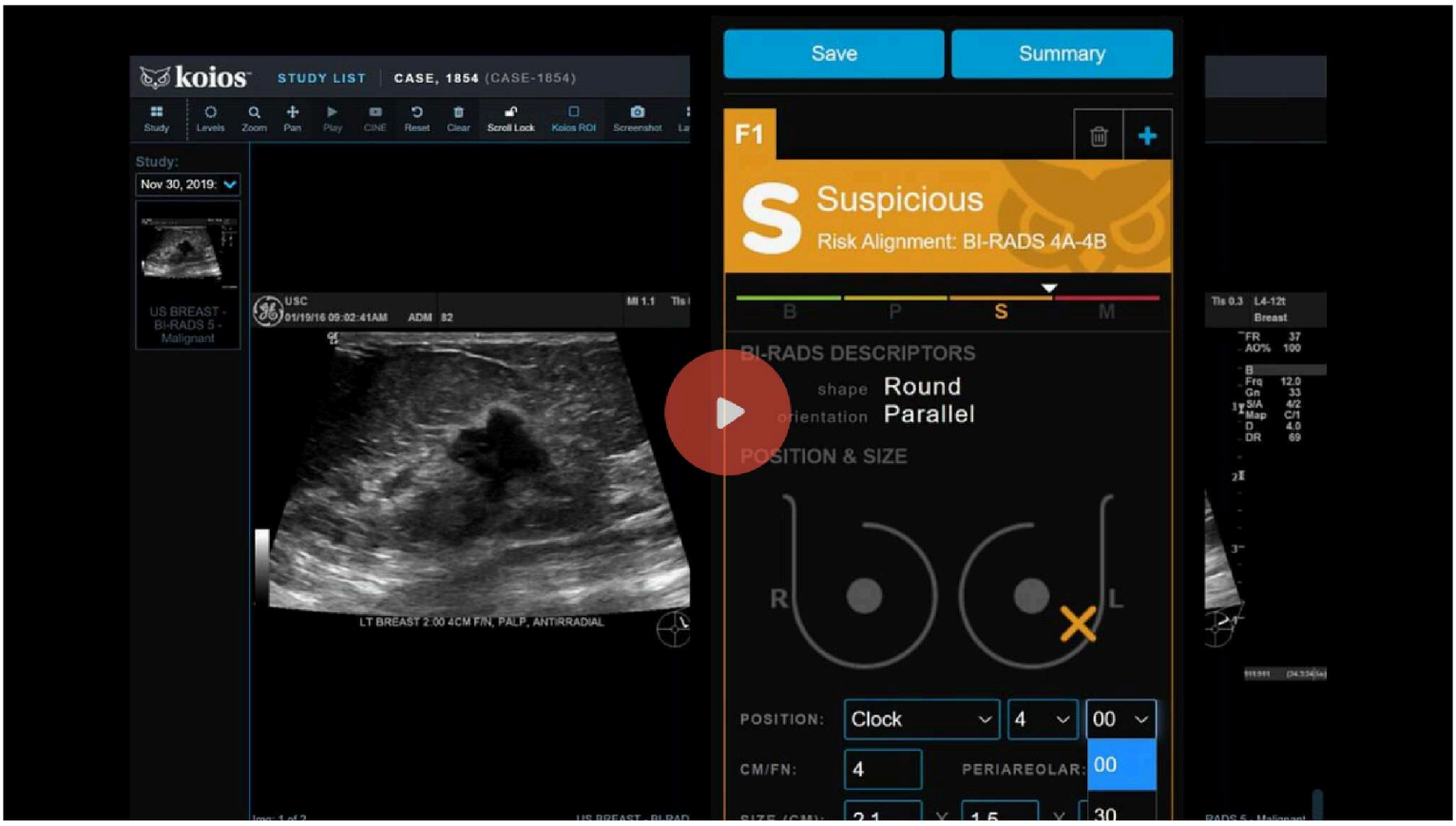

KOIOS MEDICAL, INC

A Newsweek "World's Best Digital Health Company". AI powered, life-saving software. Proven. Growing.

koiosmedical.com New York, NY

Technology B2B Healthcare AI VC-Backed

Highlights

VC-Backed
Raised $250K or more from a venture firm

Fast Growth
Revenue growing 2X/yr for at least prior 6 months

1. Rapidly growing market. AI assisted cancer detection. MRI accuracy at a fraction of the cost.

2. A Newsweek "World's Best Digital Health Company" for 2024.

3. $2B market opportunity. Worldwide network of clinical champions. 500+ sites. 35 countries.

4. Reimbursement eligible. CPT Codes (0689T, 0690T) issued. FDA, CE Mark, HealthCanada and more.

5. Disruptive AI technology. First mover advantage. Proprietary datasets. Limited to no competitors.

6. Investment terms same as lead strategic institutional investor, Mitsui & Co (Japan). >96% funded.

7. Stellar management team. Proven track record. Network of world class, engaged clinical advisors.

8. Distribution partner: GE Healthcare, Philips, Sirona Medical and more. Hyper-growth mode.

Our Team

Chad McClennan President & CEO

Leader of the company, inspired to make an impact in the lives of physicians, patients, families and society. Previous co-founder of medical software company sold to Stryker. Advised healthcare, technology companies Humana, Chapters Health System, others.

Graham Anderson Chief Financial & Administrative Officer

Graham Anderson Chief Financial & Administrative Officer

Experienced in finance across verticals including healthcare, IT services and consumer products. Former VC turned operator helping guide our company and serve our shareholders.

Ajit Jairaj Vice President - R&D

Initially designed face recognition for the US DoD and pivoted into analyzing suspicious ultrasound exams and now oversees the brilliant Koios Medical research and development engineers.

Jon Robinson Vice President - Software Product

Two decades of experience designing, delivering, and supporting radiology software products to the largest radiology providers globally.

Omar Partida Chief Development Officer

Established national breast cancer screening programs across the Gulf region, introducing and implementing innovative radiology technologies. Coordinates Koios' efforts across our growing network of channel partners.

Bill Hulbert VP Software Development

Building great software! Oversees and manages all layers of Koios application development to ensure quality, secure and reliable solutions for Koios customers.

Invest in software with vision.

We are excited to introduce you to our exciting story, the future of SmartUltrasound and offer an investment opportunity normally reserved for, exclusive to professional, institutional investors and VC firms.

Koios Medical, Inc

The global leader in AI software as a medical device (SaMD) for the accurate diagnosis of breast and thyroid cancers improving clinical outcomes and workflows applying deep learning to the lowest cost, safest and most widely available imaging modality in the world, ultrasound.
SmartUltrasound™

The first breast ultrasound exam interpretation supported by Koios SmartUltrasound was read by Dr. Lai Ming Yu in New York City on March 9,

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As of January, 2022 use of Koios DS became a billable procedure (USA).

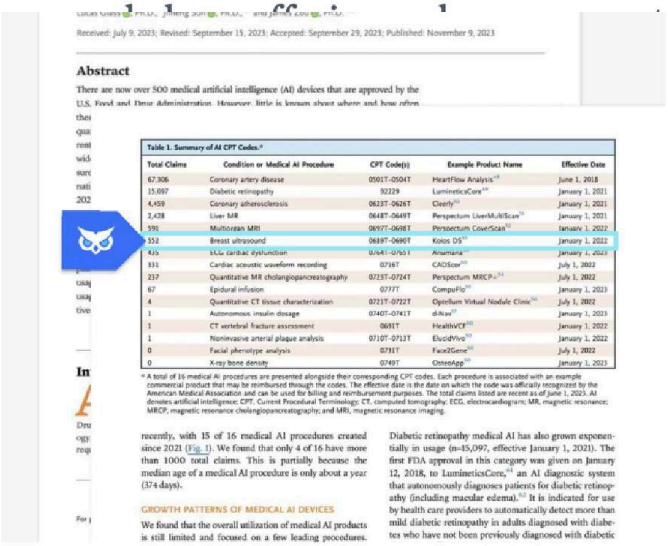
"We found that the overall utilization of medical AI products is still limited and focused on a few leading procedures.

However, utilization has generally increased exponentially for each medical AI procedure."

James Zou, PhD et al

The NEW ENGLAND JOURNAL of MEDICINE

November 9, 2023



Received: July 9, 2023; Revised: September 15, 2023; Accepted: September 29, 2023; Published: November 9, 2023

Abstract

There are now over 500 medical artificial intelligence (AI) devices that are approved by the U.S. Food and Drug Administration. However, little is known about where and how often

Table 1. Summary of AI CPT Codes.*

Total Claims	Condition or Medical AI Procedure	CPT Code(s)	Example Product Name	Effective Date
67,306	Coronary artery disease	0501T-0504T	HeartFlow Analysis[14]	June 1, 2018
15,097	Diabetic retinopathy	92229	LumineticsCore[15]	January 1, 2021
4,459	Coronary atherosclerosis	0623T-0626T	Cleerly[16]	January 1, 2021
2,428	Liver MR	0648T-0649T	Perspectum LiverMultiScan[16]	January 1, 2021
591	Multiorgan MRI	0697T-0698T	Perspectum CoverScan[16]	January 1, 2022
552	Breast ultrasound	0689T-0690T	Koios DS[16]	January 1, 2022
435	ECG cardiac dysfunction	0764T-0765T	Anumana[16]	January 1, 2023
331	Cardiac acoustic waveform recording	0716T	CADScor[16]	July 1, 2022
237	Quantitative MR cholangiopancreatography	0723T-0724T	Perspectum MRCP+[16]	July 1, 2022
67	Epidural infusion	0777T	CompuFlo[16]	January 1, 2023
4	Quantitative CT tissue characterization	0721T-0722T	Optellum Virtual Nodule Clinic[16]	July 1, 2022
1	Autonomous insulin dosage	0740T-0741T	diNav[17]	January 1, 2023
1	CT vertebral fracture assessment	0691T	HealthVCF[16]	January 1, 2022
1	Noninvasive arterial plaque analysis	0710T-0713T	ElucidVivo[16]	January 1, 2022
0	Facial phenotype analysis	0731T	FaceZGene[16]	July 1, 2022
0	X-ray bone density	0749T	OsteoApp[16]	January 1, 2023

* A total of 16 medical AI procedures are presented alongside their corresponding CPT codes. Each procedure is associated with an example commercial product that may be reimbursed through the codes. The effective date is the date on which the code was officially recognized by the American Medical Association and can be used for billing and reimbursement purposes. The total claims listed are recent as of June 1, 2023. AI denotes artificial intelligence; CPT, Current Procedural Terminology; CT, computed tomography; ECG, electrocardiogram; MR, magnetic resonance; MRCP, magnetic resonance cholangiopancreatography; and MRI, magnetic resonance imaging.

recently, with 15 of 16 medical AI procedures created since 2021 (Fig. 1). We found that only 4 of 16 have more than 1000 total claims. This is partially because the median age of a medical AI procedure is only about a year (374 days).

GROWTH PATTERNS OF MEDICAL AI DEVICES

We found that the overall utilization of medical AI products is still limited and focused on a few leading procedures.

Diabetic retinopathy medical AI has also grown exponentially in usage (n=15,097, effective January 1, 2021). The first FDA approval in this category was given on January 12, 2018, to LumineticsCore,[15] an AI diagnostic system that autonomously diagnoses patients for diabetic retinopathy (including macular edema).[3,5] It is indicated for use by health care providers to automatically detect more than mild diabetic retinopathy in adults diagnosed with diabetes who have not been previously diagnosed with diabetic

Ranked #6 of most frequently billed AI solutions of the more than 700 AI solutions cleared by the FDA; all in less than 18 months since codes for the use of Koios DS were made available. Research indicates the availability of billing codes can lead to utilization that grows "exponentially".

Situation

AI-powered software for ultrasound imaging and workflow optimization is poised to super-charge an already booming market.

Projected market value of ultrasound, by 2028. **$13B**

The global medical imaging AI market is **$14B**

As of January, 2022 use of Koios DS became a billable procedure (USA).

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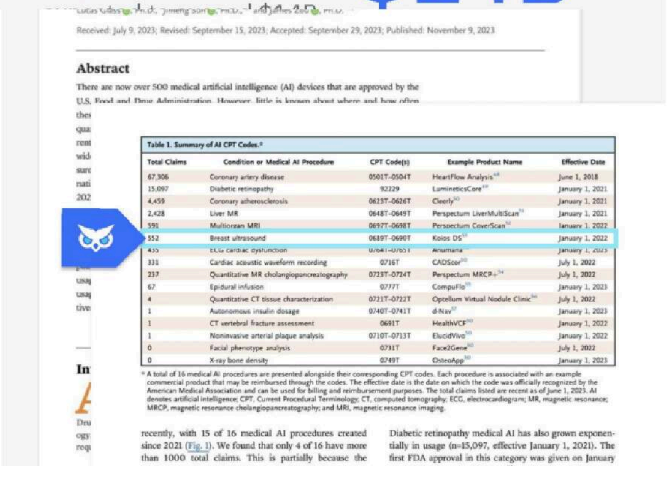
The NEW ENGLAND



JOURNAL of MEDICINE

November 9, 2023

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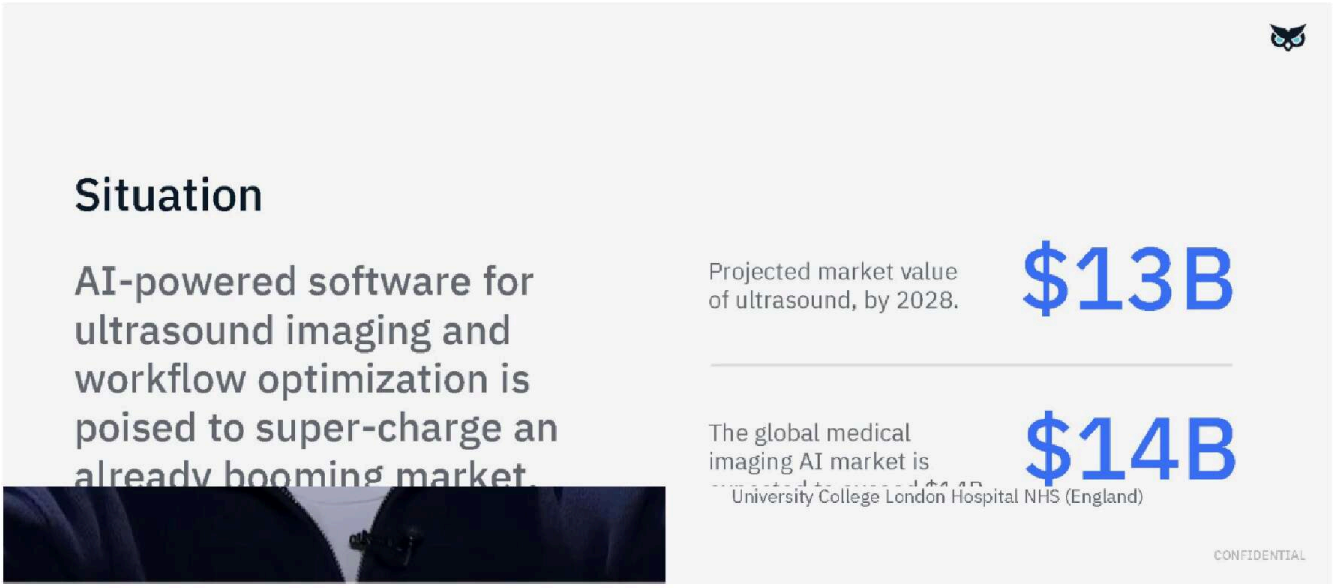
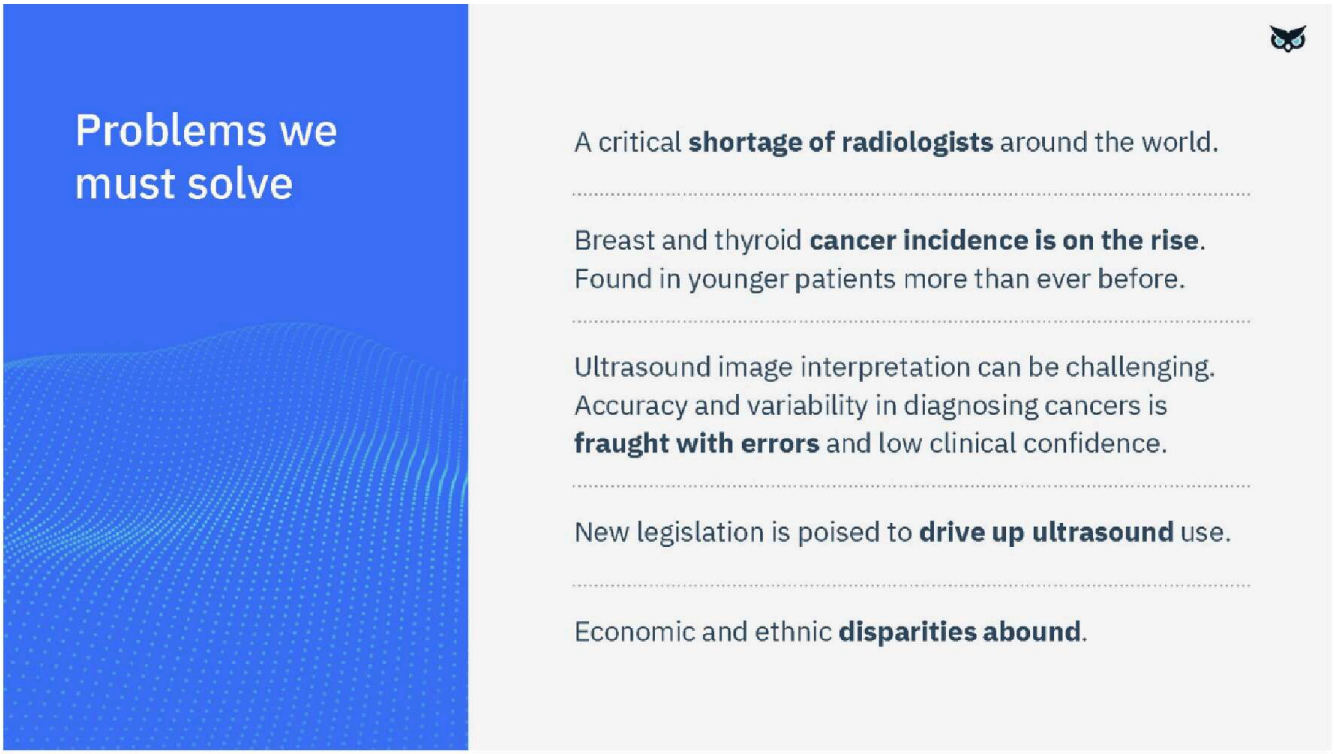
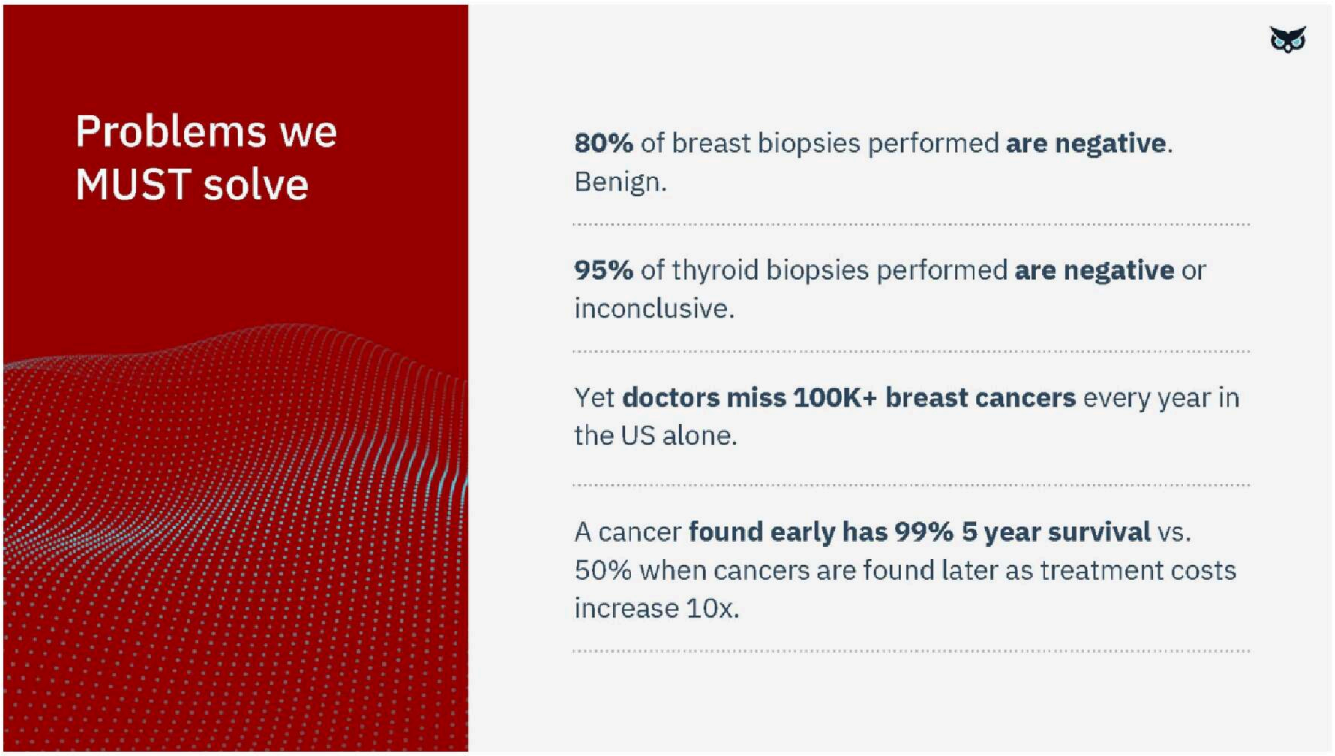


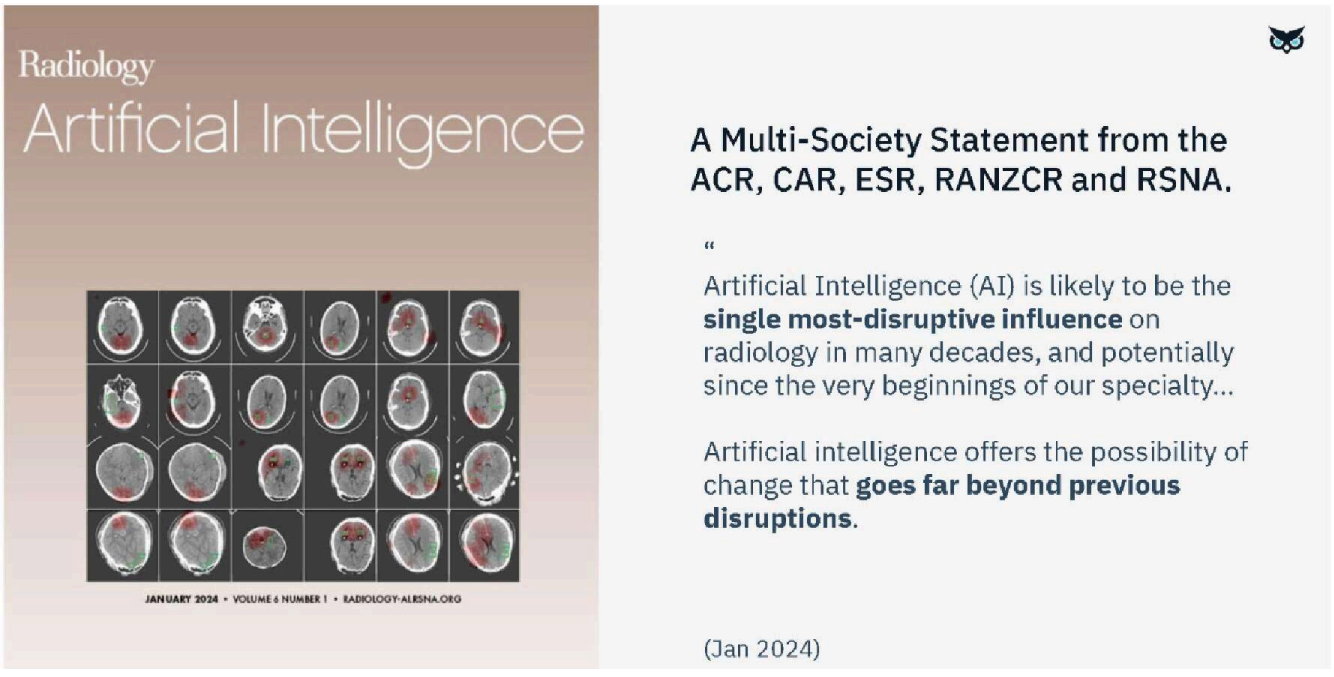


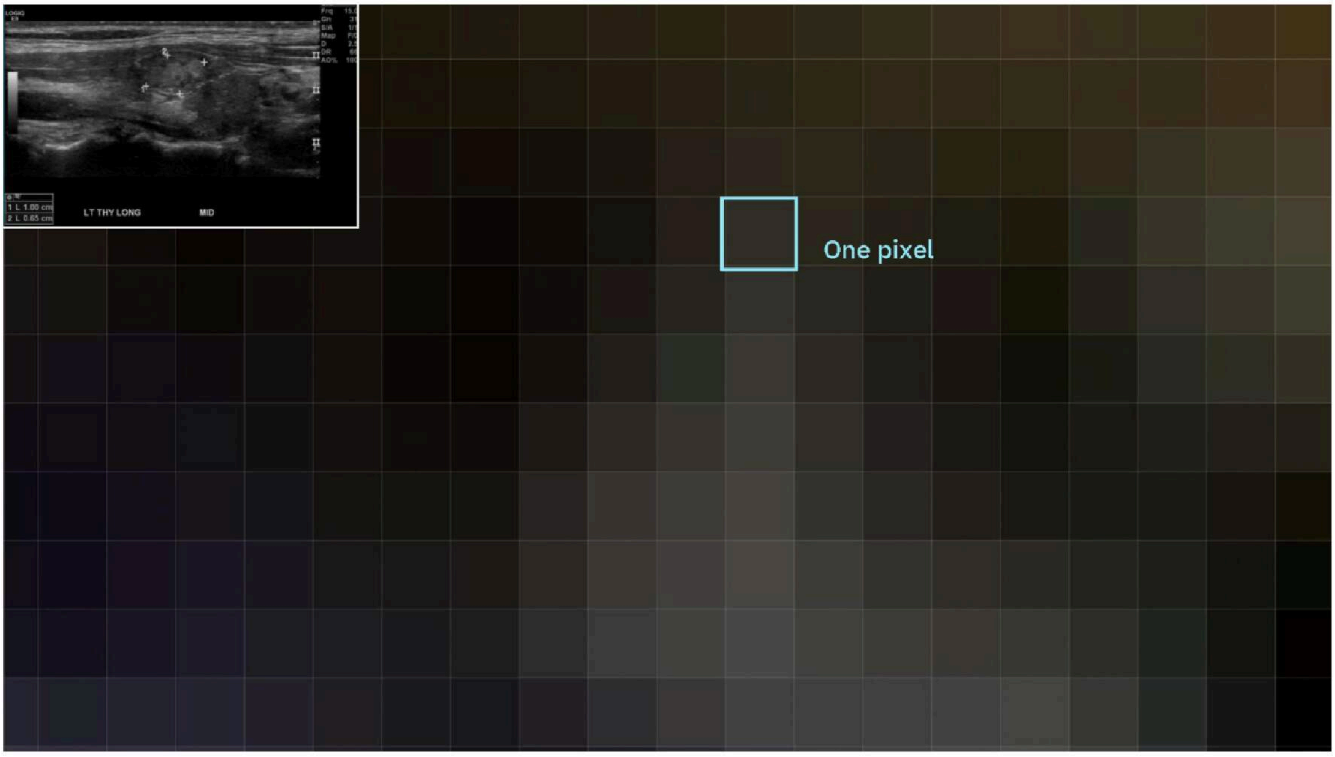
Koios Medical's software was designed at the outset to pinpoint multiple pain points plaguing healthcare systems worldwide; specifically radiology, the mega service line that spans across all medical specialties. A "one to many" relationship exists whereby a single software solution can elevate quality, control costs, save

time and help close the health equity gap simultaneously.



Lives are at stake. Although many solutions offer a promising range of benefits, few can match the life-saving impact of early cancer detection and accurate diagnosis. $1.6B is spent annually in the US on breast biopsies of which $1.3B are benign, negative; YET tens of thousands of breast and thyroid exam still miss, or deem as "interval cancers" to be found later, often after the possibility of effective treatment. Koios SmartUltrasound is already saving lives along with ultimately millions of dollars and hours of time wasted on avoidable procedures and too late-stage treatments.

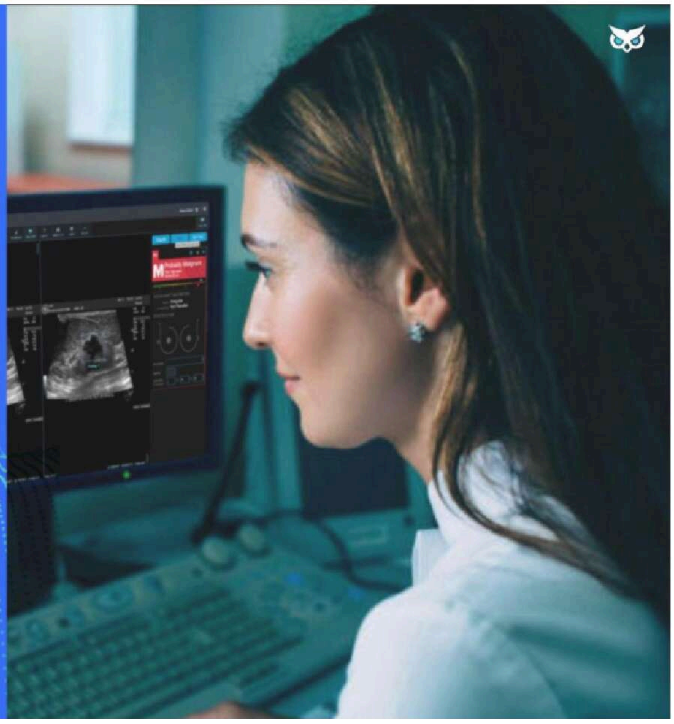




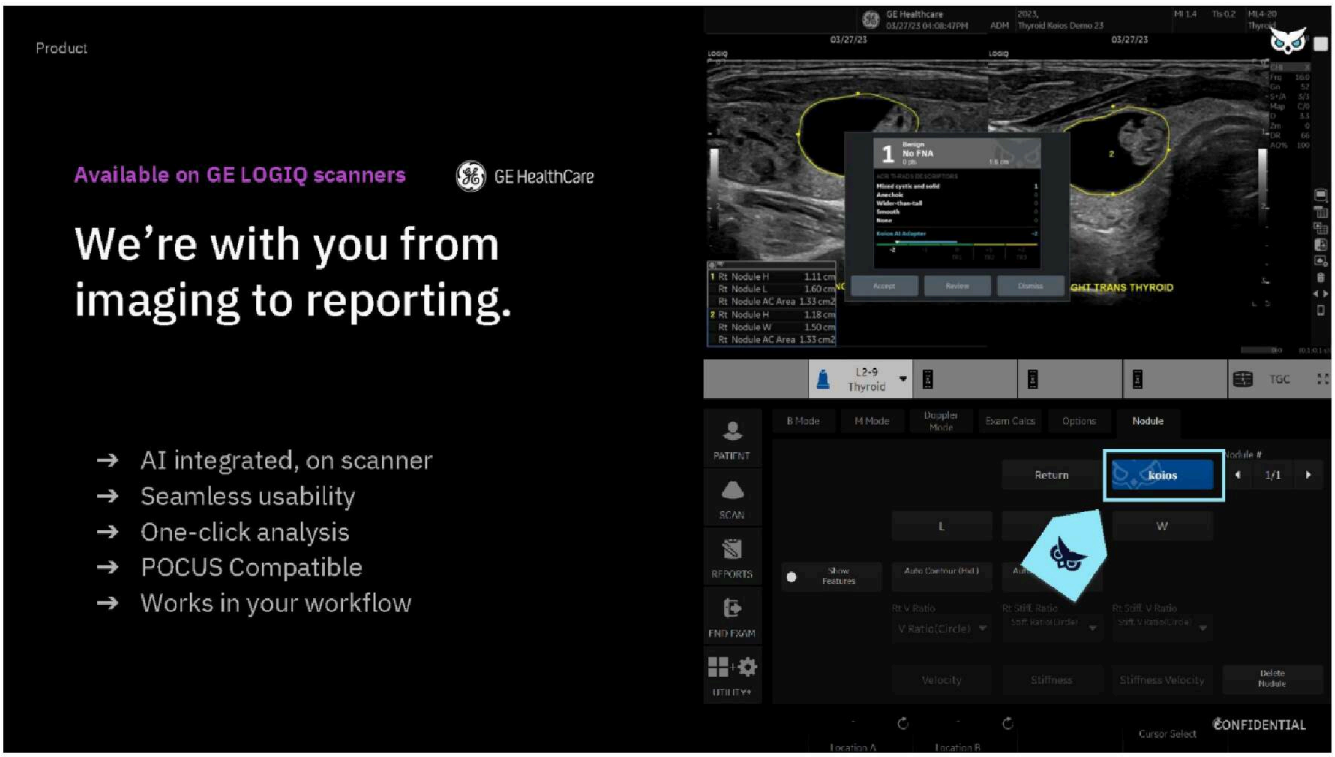
SmartUltrasound was created from amassing a dataset comprised of what has grown to over 2M images along with pathology data that distills images down to the pixel level for patterns that are invisible to the human eye, building models that predict cancer and distinguish normal tissue with startling and ever increasing accuracy. Trillions of pixels tell a story that saves lives and reduces the need for the cost and stress of more crude methods of today.

SmartUltrasound
Scalable, accurate, simple, fast.

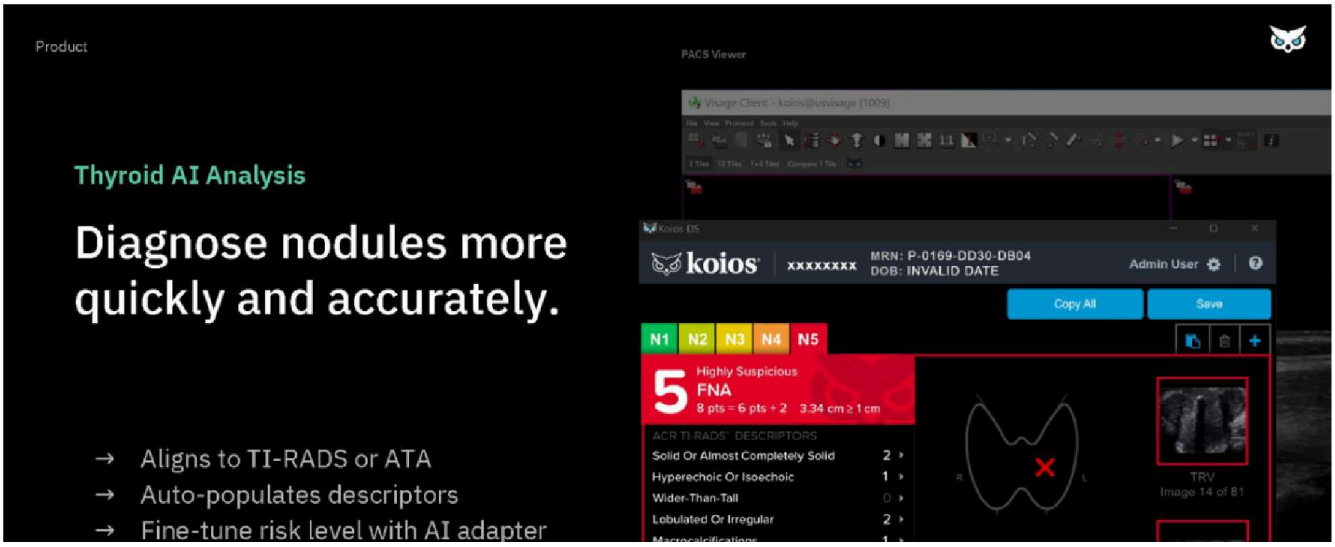
On scanner, at your workstation, in your reports.



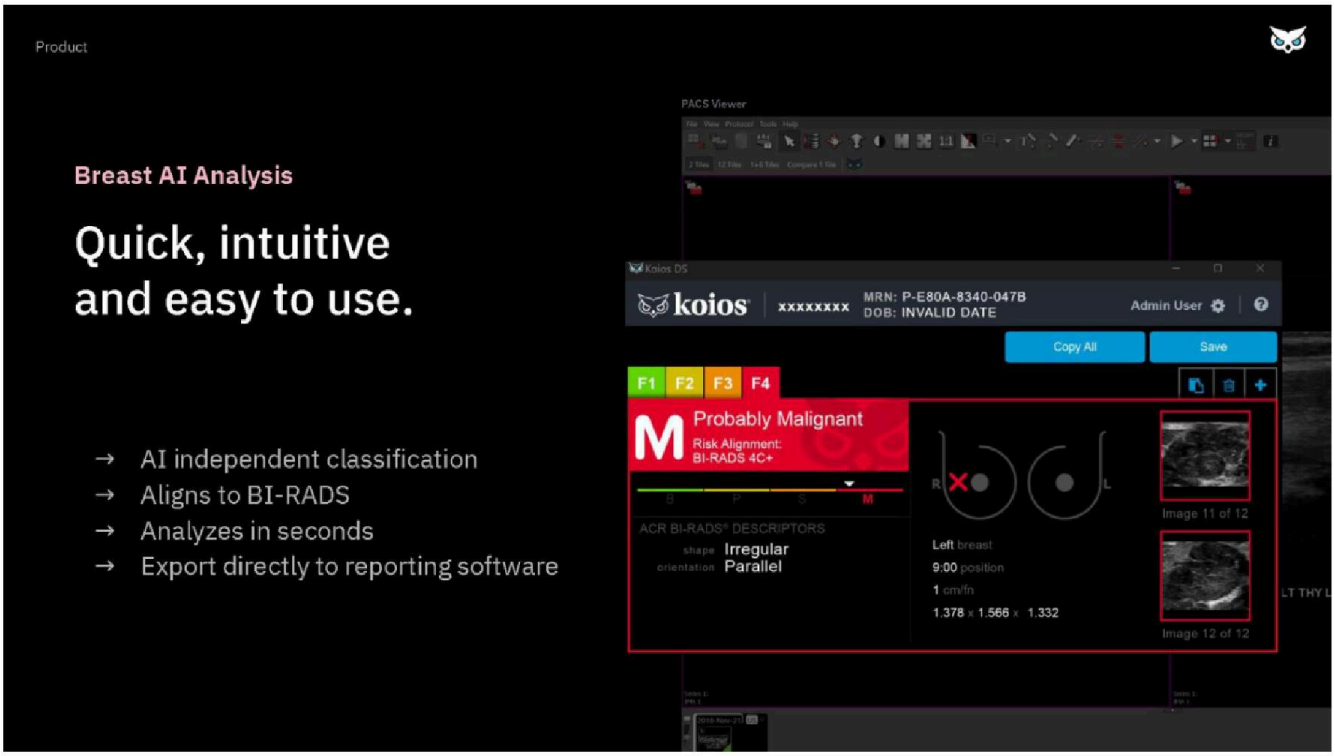
Our software is designed and built to meet the needs of clinicians from on-scanner in the ultrasound exam room to the reading workstation and into reports. Vendor agnostic built upon image data from all major ultrasound scanners across all major ethnicities. Built for a global community of users and patients to improve accuracy, consistency and optimize cumbersome workflows.



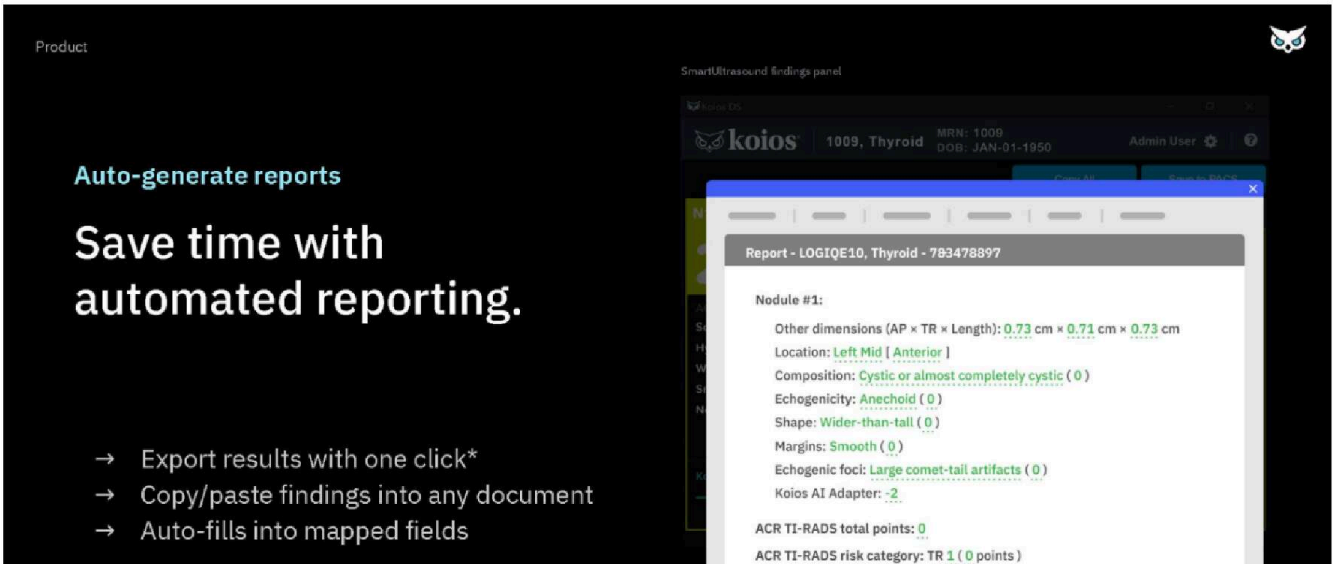
Simply select the Koios Owl button directly on the touch panel of any GE LOGIQ scanner and instantly obtain a cancer risk assessment aligned to BI-RADS or TI-RADS that can be edited, saved or disregarded, improving timeliness of interpretation with fewer reporting errors. Coming soon to the touch panel of other major manufacturers.

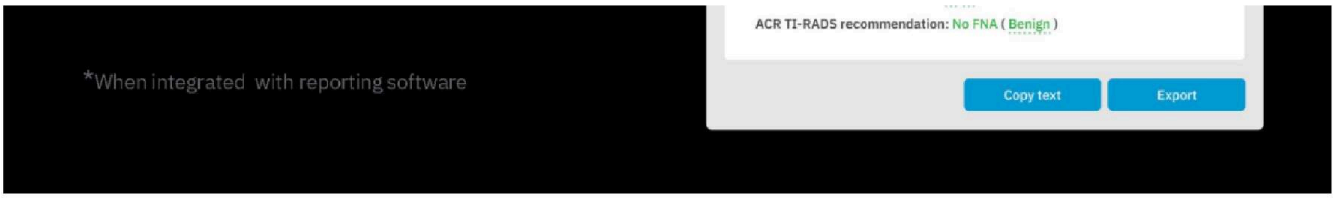


Multiple suspicious nodules captured in a thyroid ultrasound exam receive a full and thorough assessment, classified and a draft report prepared aligned to TI-RADS and ready for review. Modify or export directly into patients' reports.



Ultrasound breast exams, particularly valuable to women with dense breast tissue, benefit from a thorough cancer risk assessment aligned to BI-RADS to be saved, edited and exported directly into patients' reports.





Full reports can be populated at the lesion or nodule level with each appropriate descriptor category populated, TI-RADS scores calculated and exported into a consistent, customized report template complete with CPT Codes and language to facilitate accurate billing.

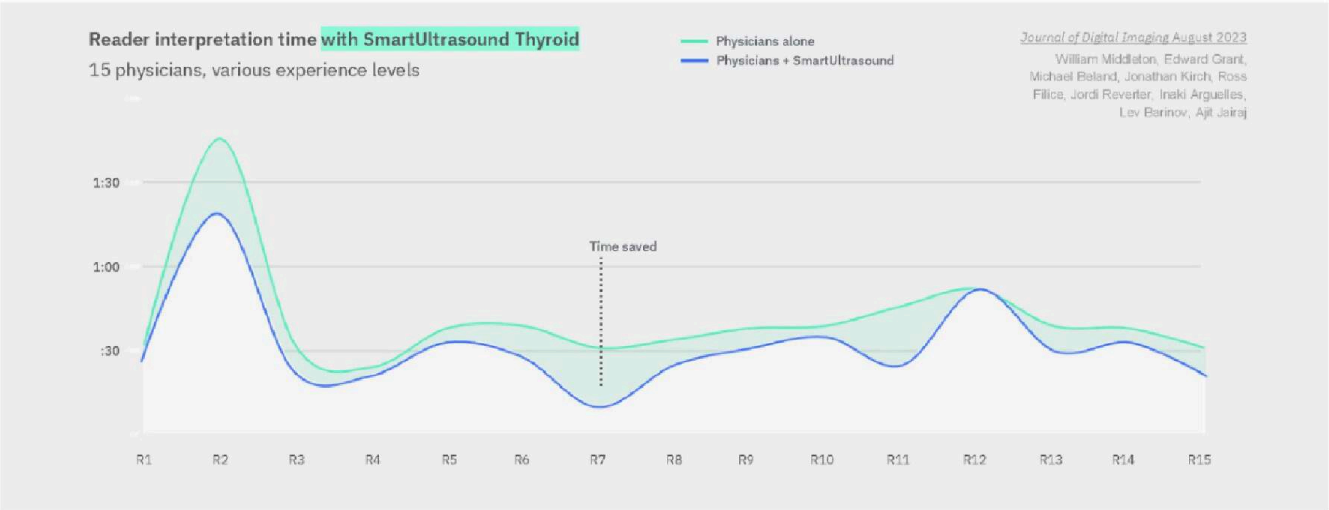
Why is Koios DS SmartUltrasound software SO important? Nobody is correct 100% of the time. In fact, Koios' and other studies have found physicians can disagree with one another on examination interpretation more than 1/3 of the time AND will change their minds on the same exam one of every five times. Variability in interpretation leads to errors. Medical mistakes are the 3rd leading cause of death in the US. Use of Koios software dramatically reduces variability by >40%.

Koios' landmark study was comprised of 15 physicians across all experience levels and found significant improvements to both sensitivity (cancer detection) and specificity (benign determination) leading to significant improvements to the overall quality of care and patient outcomes (at lower costs).

Evidence

Our AI makes *everyone* faster.

Sensitivity (avg.)	+14%	Variability	-41%
Specificity (avg.)	+37%	Interpretation time	-24%



Not only was quality improved, but significantly LESS time was required when studying physician interpretation times.

Evidence

11

Peer-reviewed retrospective studies

20

"

The AI DS accurately characterized 100% of detected ILC lesions as suspicious or probably malignant.

Clinical Imaging May/Sept 2023

Tali Amir, Kristen Coffey, Varadan Sevilimedu, Reza Fardanesh, Victoria L. Mango

"

Artificial intelligence decision support aid may help improve sonographic diagnostic accuracy, ... decreasing false-

Posters and abstracts

50*

Validation studies

*And counting

positives.

Ultrasound Quarterly March 2021

Samantha L. Heller, PhD, MD; Melanie Wegener, MD; James S. Babb, PhD; Yiming Gao, MD

"

Our results suggest that software like this could potentially reduce the number of unnecessary breast biopsies.

2020 SBI ACR Breast Imaging Symposium

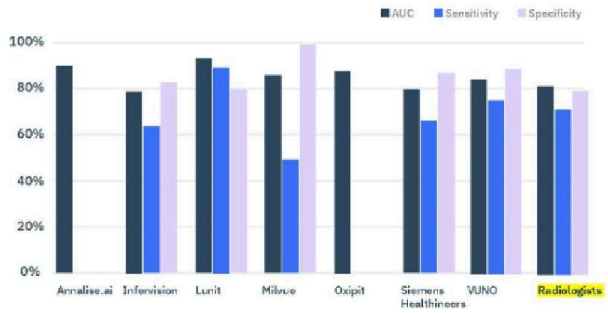
Joseph Cavallo, MD *2020 Wendell Scott Research Award Recipient*
Fellow, Emergency Radiology & Healthcare Leadership
Yale Department of Radiology

All studies performed to date all indicate the same, powerful and exciting conclusion: Koios SmartUltrasound software when used properly and in accordance with its indications can lead to significant improvements in cancer detection while simultaneously eliminating avoidable benign biopsy procedures and unnecessary follow-up appointments for patients.

Evidence

It's happening, AI outperforms.

A Comparison of AI Vendor Algorithms for Stand-Alone Lung Nodule Detection on Chest X-Rays



Source: Leeuwen KG, Schalekamp S, Rutten MJCM, et al. Comparison of commercial AI software performance for radiograph lung nodule detection and bone age prediction. *Radiology*. 2023;210(1):e23091. Doi: 10.1148/radiol.230981. Online ahead of print. *(Editor's note: Sensitivity and specificity percentages for the Annalise.ai and Oxipit algorithms were not available in the study.)*

- → Multiple AI solutions have begun to consistently outperform physicians.
- → Several companies, clinical use cases.
- → **Koios SmartUltrasound + physicians consistently outperforms physicians alone.**

CONFIDENTIAL

AI is outperforming physicians alone in other clinical applications as well. A recent study demonstrated how several solutions performed relative to physicians interpreting the same exams. NOTE: Koios is indicated for use as a second opinion, to complement and augment clinical decision-making.

Metrics

Koios KPIs: Adoption Accelerating

Trailing 6 Months:

Trailing 6 Months:

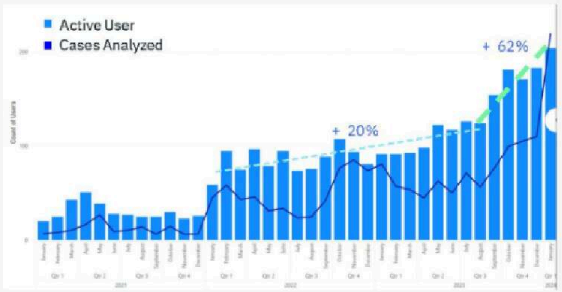
→ Active Users: **+ 62%**

→ Cases Analyzed: **+ 207%**

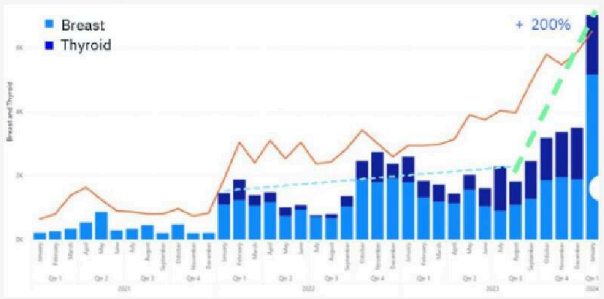
→ Breast Exams: **+ 376%**

→ Thyroid Exams: **+ 154%**

Active Users



Cases Analyzed



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Key metrics: User and adoption growth has experienced double and triple digit gains since emerging from the Covid challenged period that began March, 2020. Adoption growth is the precursor to revenue we anticipate in the future as trials and pilots convert to commercial terms.

Traction

Rapidly Growing Customer Base

A growing community of key opinion leaders (KOLs) and distributors actively advancing AI adoption.

USA
California
Colorado
Connecticut
D.C.
Florida
Illinois
Kansas
Maryland
Massachusetts
Michigan
Missouri
New Jersey
New York
North Carolina
Ohio
Pennsylvania
Rhode Island
Texas
Vermont
Virginia
Washington

Canada

EMEA
Belgium
Czech Republic
Egypt
France
Germany
Greece
Ireland
Israel
Italy
Kenya
Kuwait
Lithuania
Moldova
Morocco
Netherlands
Romania
Saudi
Spain
Turkey
UAE
United Kingdom
Qatar

APAC
Indonesia
Malaysia
Singapore
Thailand
Vietnam

LATAM & CARIBBEAN
Mexico
Venezuela
Dominican Republic
Argentina
Chile
Peru
Guyana
Ecuador
Uruguay
Brazil

60
data sources

30+
distributors

30+
research sites

*as of Nov 2023

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Traction

Adoption

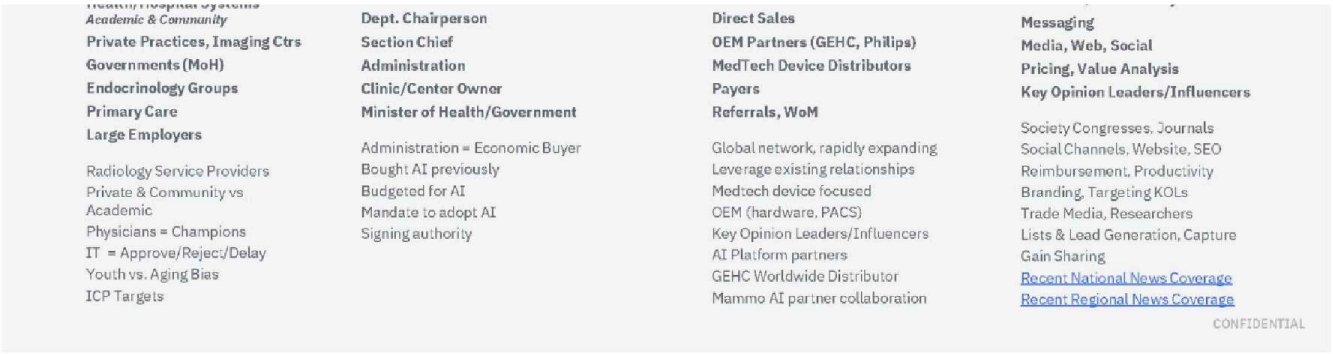
Forward-thinking organizations around the world are

SaludDigna
Yale NewHaven Health
RadNet
Memorial Sloan Kettering Cancer Center
MedStar Georgetown University Hospital
NHS Grampian
MD Anderson Cancer Center
Dexeus mujer
Duke University

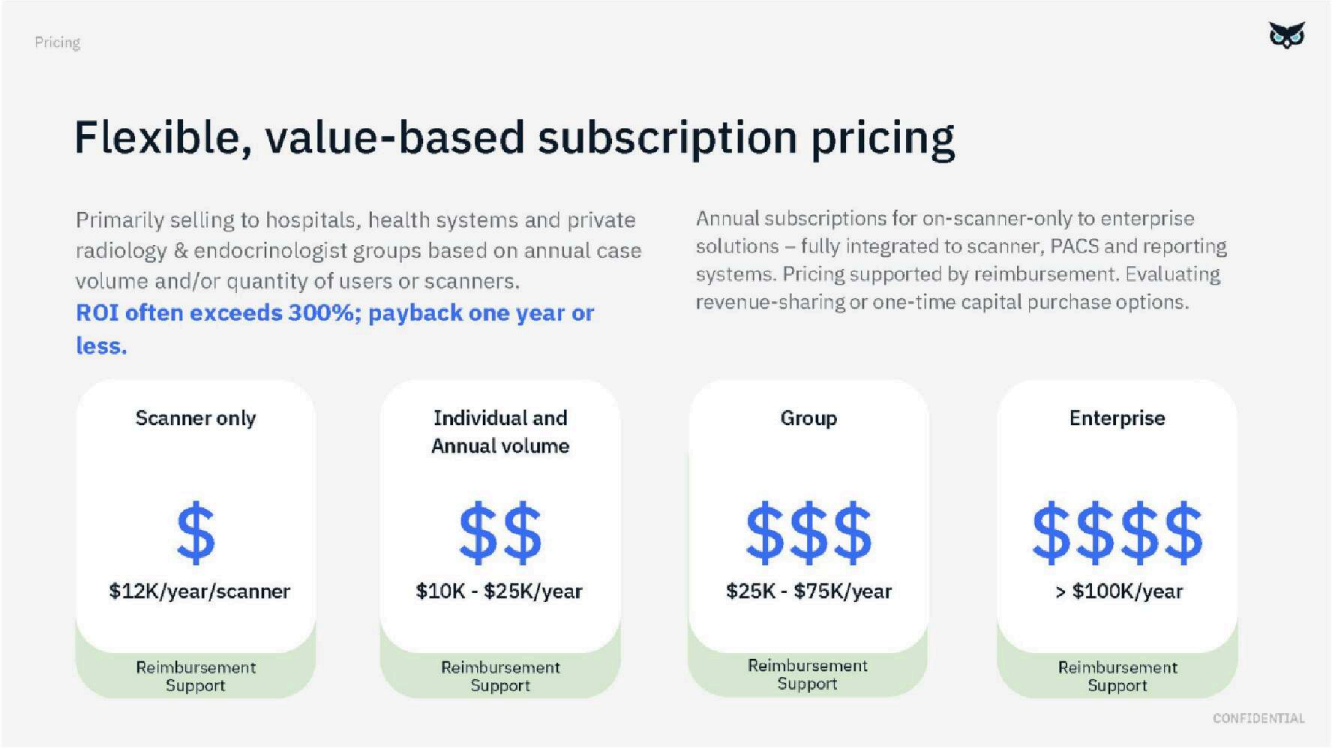
A sampling of customer institutions and organizations (willing to allow us to display their names). Many of the leading cancer centers in the US are customers and/or research partners among a rapidly growing installed base.

	Ultrasound	X-ray/Mammo	CT-scan	MRI
Breast	Koios Samsung Qview SeeMode	Kheiron CureMetrix iCAD, Screenpoint Deep Health Therapixel, Lunit		Qlarity *Formerly QuantX*
Thyroid	Koios AmCad MEDO			
Lung/Chest		(several)	Riverrain AIdoc	
Brain			Viz.AI AIdoc Others	(Several)
Abdomen	Butterfly		GE	Resonance
Heart	Caption Health Heart Flow		Siemens TeraRecon	Arterys (several)

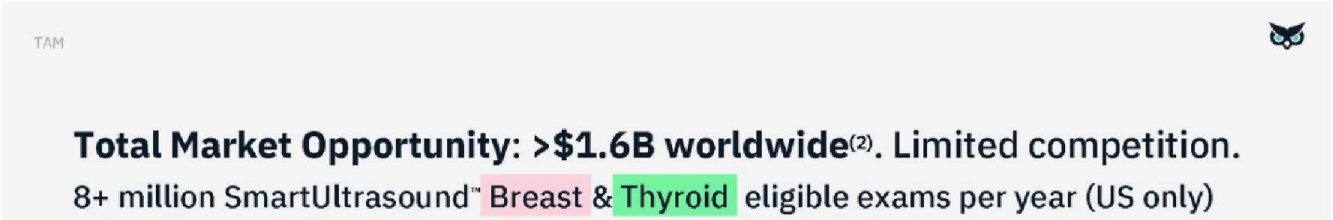
Koios enjoys a first mover advantage and a unique position with limited to no known viable competition worldwide. Other ultrasound AI players either lack similar capabilities or are yet to receive regulatory approvals and clearances.

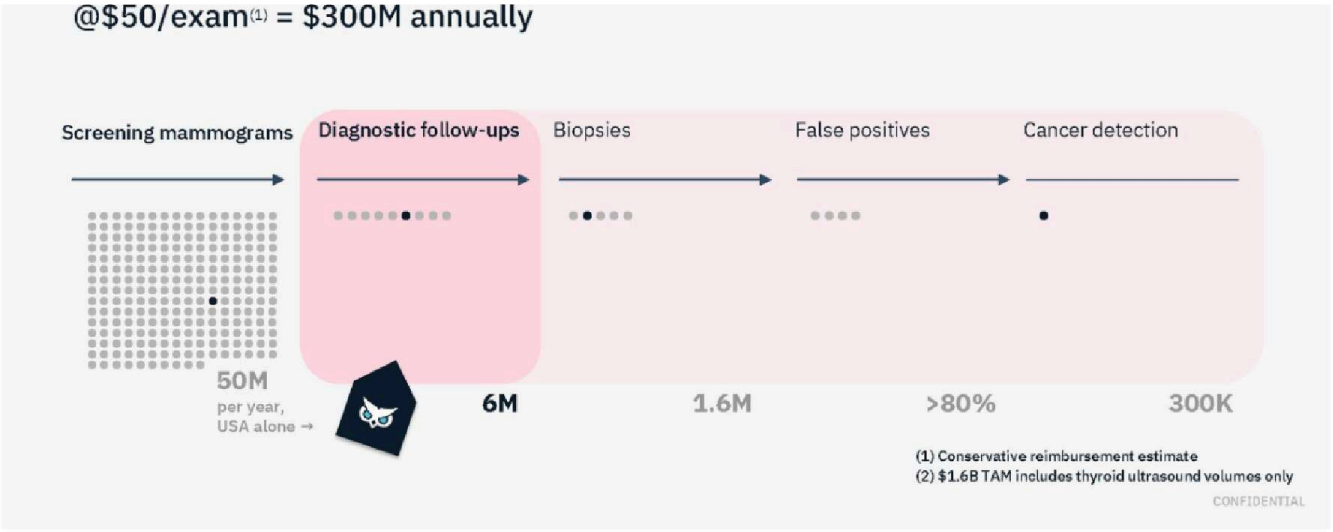


A "go to market" strategy and plan in full execution mode. Targeted customers being reached through a coordinated effort of campaigns, conferences and distribution partners with flexible, value-based pricing. Our global distribution network included GE Healthcare, Philips, Sirona Medical and many other leading regional and local entities.

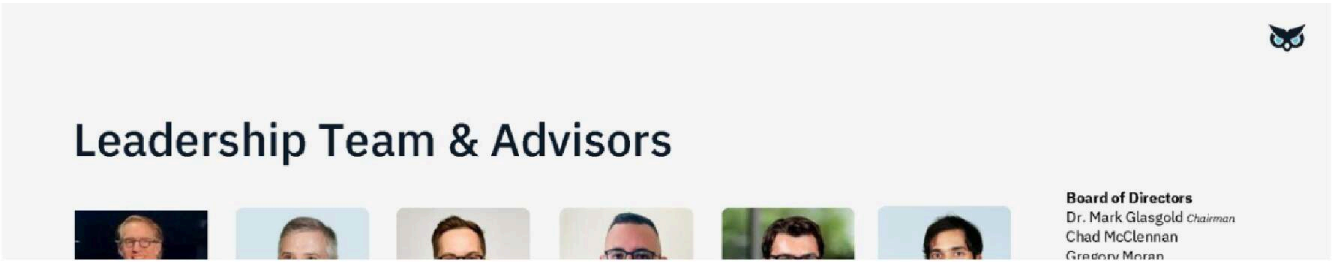


Annual subscription pricing tailored to the size of any customer. Investments in Koios software typically costs far less than the gains, efficiencies seen and amounts eligible for reimbursement, typically delivering a payback measured in months. Arguably the strongest value proposition available of any radiology AI solution.





Millions of traditional diagnostic exams per year are now eligible, candidates for the use of Koios SmartUltrasound, creating a substantial market opportunity for Koios and our distribution partners.



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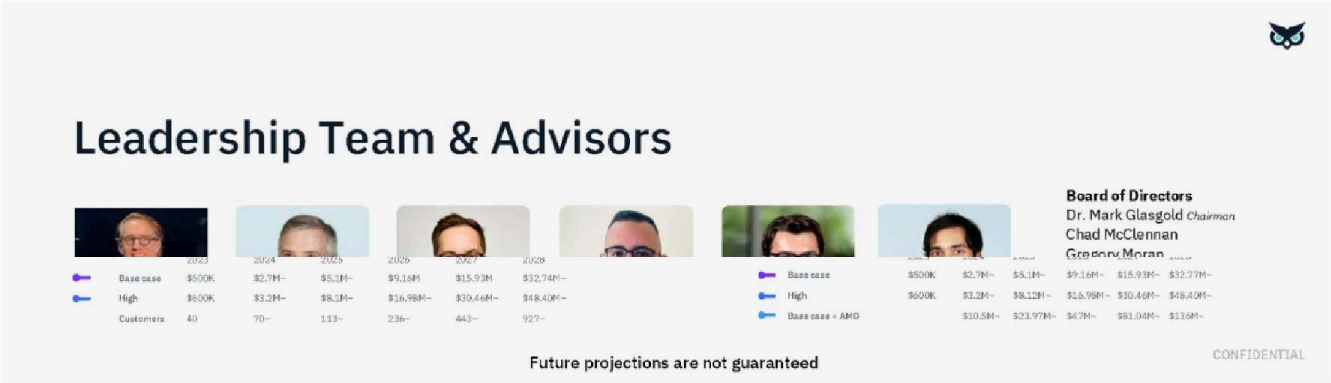
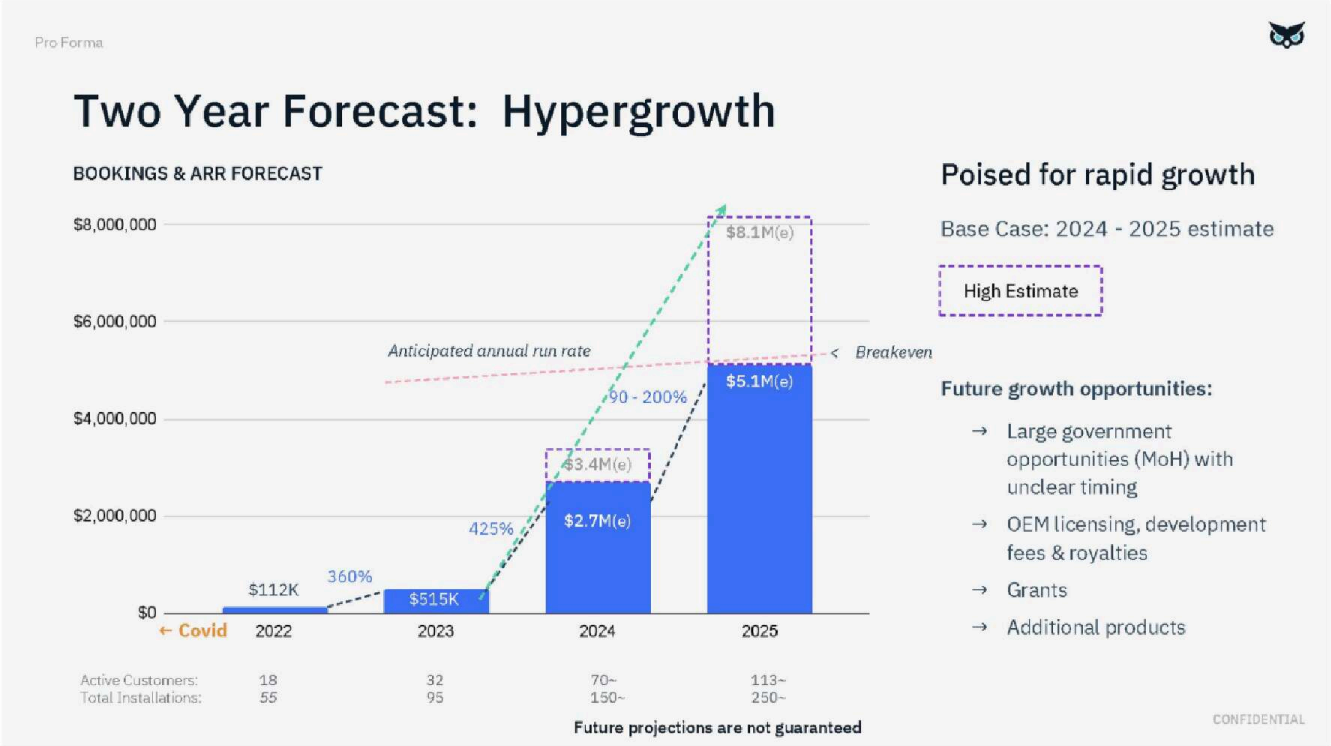


Growth projected for 4-5 years in the future may offer an opportunity for investors to exit through either acquisition or future financing rounds used for additional product and market development, expansion. Future projections not guaranteed.



Current forecasts indicate the potential for achieving cashflow neutral to positive by the end of 2025. This current raise could be sufficient to achieve that important milestone. Note that future projections are not guaranteed.

Prior (Series A) **Round:** **$10M** raised at **$25M** *(pre-money)*

Koios Medical has efficiently utilized $34 million in seed and venture capital since its inception in 2012. Currently, the company is in the process of raising an additional $5 million through WeFunder, in conjunction with a Series B round led by Mitsui & Co, of which $8 million has already been committed and funded.

Our objective is to source incremental funds from a diverse network of passionate individuals dedicated to innovation and enhancing healthcare. WeFunder provides an avenue for Koios to extend this investment opportunity to physician customers, patients, partners, and other healthcare investors that might otherwise be restricted to institutional investors.

With Mitsui as the largest shareholder in IHH Healthcare and our global community of physician customers, partners, and individual investors, we are confident that Koios will be well-positioned to execute its aggressive growth strategy. Our ultimate aim is to establish Koios as the global standard for diagnostic ultrasound, reducing missed cancer diagnoses, facilitating early cancer detection, optimizing workflows, expediting reimbursement processes, and fostering rapid global commercial expansion.

Koios Medical has already demonstrated promising results in the US market, with multiple private payers reimbursing our SaMD technology under recently approved CPT codes (0689T, 0690T) applicable to both Koios DS Breast and Thyroid SmartUltrasound AI software. Additionally, the newly created Medicare Transitional Coverage for Emerging Technologies (TCET) presents another favorable payment framework opportunity through CMS.

Furthermore, the growing shortage of clinical resources worldwide, coupled with the escalating imaging workload, underscores the urgent need for an innovative imaging solution to enhance productivity and prevent lapses in care, excessive treatment costs, and loss of life.

The allocated funds will primarily deployed as working capital to support commercial expansion, ongoing market and product development, enhancing efficiency for physicians and technicians, reimbursement efforts, and continued support for our expanding customer base transitioning to commercial customers and product advocates. This growth capital will facilitate expanded market access, reimbursement support from payers, operational scaling in key markets, data acquisition, and funding operations while implementing new monetization strategies.

The infusion of Series B equity/crowdfunded growth capital will drive clinical adoption necessary for SmartUltrasound™ to establish itself as the diagnostic standard worldwide, laying the groundwork for robust revenue growth and profitability in 2026 and beyond.

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Koios Community Testimonials

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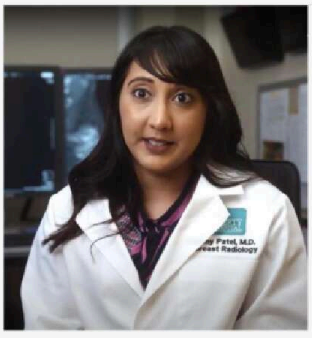


"Koios artificial intelligence nearly cuts my reading times in half, especially on more challenging and time consuming cases... those minutes really add up."

Amy Patel, MD
Chief of Breast Imaging, Liberty Hospital & UMKC Medical School

"What Koios was able to do in 5 seconds typically requires 3 minutes, per nodule AND did so with perfect accuracy..."

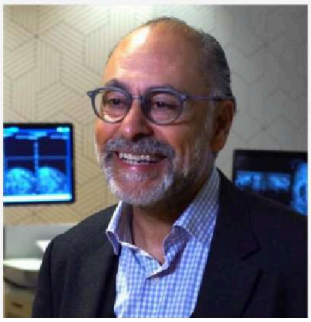
Dr. Julian Goh Park Nam
Tan Tock Seng Hospital, Singapore

"Koios is transforming thyroid nodule characterization and markedly improving the lives of patients with nodules.

Decreasing unnecessary biopsy for benign nodules while accurately identifying thyroid cancer, Koios powered by AI allows us to navigate a new world in next generation thyroid imaging.

Your patients and referrers will thank you for being Koios confident!"

Louis Mazzarelli, MD
Radiologist, Yale New Haven Health/Lawrence + Memorial (USA)



"Koios AI has profoundly influenced our medical practices, bringing about a substantial reduction of nearly 50% in excessive follow-ups for BI-RADS 3 cases.

Additionally, we've observed an almost one-fifth decrease in biopsy indications for BI-RADS 4 cases.

Koios AI has effectively streamlined our processes, leading to improved efficiency in breast imaging."

Professor Erkin Aribal, MD
Chief of Breast Imaging, Acibadem University (Turkiye)

"Artificial intelligence has the ability to make us... even better physicians than we might otherwise be.

Laurie Margolies, MD

Chief of Breast Imaging, Mount Sinai Health System

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CBS Evening News Segment:
https://www.cbsnews.com/newyork/news/doctors-tout-use-of-artificial-intelligence-to-detect-breast-cancer/

Koios Medical, Inc

Investment Opportunity Summary

Koios Medical, Inc (NYC) has emerged as the global leader in AI software for accurately diagnosing cancer while improving clinical workflows by applying proven machine learning to the lowest cost, safest and most widely available imaging modality in the world: ultrasound, sonography

Koios SmartUltrasound software is built upon proprietary machine learning and deep learning models and methods, utilizing a massive and expanding image dataset clinically proven to enhance diagnostic accuracy for breast and thyroid cancer while optimizing operational workflows.

The Company holds regulatory clearances both domestically and internationally (FDA, CE Marks) as software as a medical device (SaMD), providing clinical decision support to improve physician efficacy, efficiency, and productivity. This technology is currently utilized by a growing network of leading caregivers spanning over 20 countries.

Koios Medical is positioned for exponential growth over the next five years as the adoption of AI in radiology, particularly, gains traction in response to workforce constraints. This growth is supported by our accumulating body of positive clinical evidence, ongoing product innovations, a global distribution network, increasing user acceptance, and the rise in payer-supported reimbursement.

The Company is currently raising a Series B round of $13M with $8 million already committed and funded by a major international financial institutional investor (Mitsui & Co). An additional $5 million is available for raising from the "Koios Community" through WeFunder.com/Koios.

Thank you.

Chad McClennan
President & CEO

Graham Anderson
CFO, CAO

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