



## **Koios Medical Year in Review, Look Ahead & Funding Update**

### **Dear Fellow Investors,**

Team Koios closed out 2023 reflecting upon another year of tirelessly working to advance clinical adoption while improving system performance of our proven, innovative, lifesaving, AI-enabled technology for detecting and diagnosing cancer. “Long Covid” also had a devastating effect on healthcare systems around the world well into 2023. Residual damage was done to the economic, technical and labor landscapes of healthcare overall and radiology in particular. We remain steadfastly propelling forward knowing lives are at stake, livelihoods hang in the balance and the world is rapidly evolving into the reality of an AI enabled future. The world is awakening to a new culture of collaboration with AI, becoming a “need to have” that moves past earlier experimental periods from our recent past.

Working together with our customers, advisors and partners we are creating a truly groundbreaking solution for Radiology AI; a category that never existed prior to 2018 when we emerged onto the scene. Last year was characterized by a “slowly but surely” mindset and sentiment shift. Momentum is building at the pace of change in healthcare, universally acknowledged as slower than most industries, but rightly so. We must all move forward together responsibly, relying heavily on data that takes time, but is required to be confidently accepted into the medical ecosystem.

Our operational and financial metrics are telling an exciting story of this new upward trend. Our year in review includes select highlights, milestones, accomplishments along with our exciting future and funding plans. Thank you again for your consistent interest and support.

### **2023 Themes:**

- The debate rages, “Who Should Pay for AI”? *Our CPT Codes help answer this question.*
- Caution abounds. Pilot, test, measure, measure again. *We patiently, persistently proceed.*
- Reimbursement is still met with skepticism. *We build more champions and case studies.*
- Proliferation of AI companies is slowing, select few “use cases” emerge as early winners.
- An AI strategy has become a “must have”. *We are the “only game in town” for ultrasound.*
- Early adopters are maturing into advocates. *Our Koios Community spans the globe.*



**Important January Announcement:** A Multi-Society Statement from the ACR, CAR, ESR, RANZCR and RSNA. (Radiology|AI Journal) *Six of the largest radiology societies in the world coming together to make a joint statement about AI.*

“Artificial Intelligence (AI) is likely to be the single most-disruptive influence on radiology in many decades, and potentially since the very beginnings of our specialty...

Artificial intelligence offers the possibility of change that goes far beyond previous disruptions.”

**Media & Patient Advocates:** *Koios software, our wise Owl prominently showcased throughout, demonstrates how we are becoming a cornerstone solution in any AI strategy for breast imaging.*

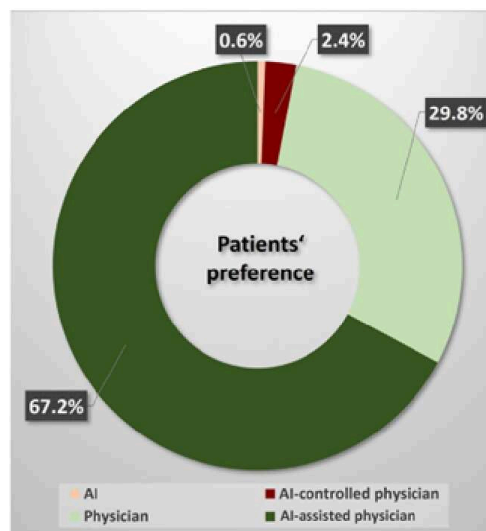
CBS News (Regional)

[Doctors tout use of artificial intelligence to detect breast cancer - CBS New York \(cbsnews.com\)](#)

CBS Evening News (National)

[How AI is bringing new options to mammograms, other breast cancer screenings - CBS News](#)

A recent European study found that patients prefer an “AI-assisted physician” more than two to one over a “physician only” for a diagnostic decision.



Source: European Urology Focus (Nov 1, 2023).

[https://www.eu-focus.europeanurology.com/article/S2405-4569\(23\)00237-7/abstract](https://www.eu-focus.europeanurology.com/article/S2405-4569(23)00237-7/abstract)



## Account Growth

Several major accounts commenced pilot installations & validation including:

- Kaiser Permanente
- RadNet – Thyroid (East & West coasts)
- Yale – Thyroid
- Northwell – Thyroid
- Dexeus Mujer – Spain (*signed*)
- Salud Digna – Mexico (*signed*)

## Active Accounts

- 2023: + 62.7%
- 2024: + 24.4% (Q1 vs. 12/31/2023)

## Adoption Growth (2023 vs 2022)

- Registered Users: 435 (+38%)
- Breast Lesions Analyzed: 16,991 (+20%)
- Thyroid Nodules Analyzed: 10,854 (+140%)

## Bookings Growth (Actual & Projected)

- 2022: \$ 110K
- 2023: \$ 515K (+ 360%)
- 2024: \$2.4Me (+ 385%)
- 2025: \$6M+e (+ 250%; cash flow positive)

## Product Advancements (SmartUltrasound™)

Diagnostic Accuracy: Our newest “AI engines” under development (in the “Koios Lab”) for the past 2+ years are proving to deliver significant, measurable accuracy improvements over the currently FDA cleared version in market today due to the acquisition and integration of very difficult to come by large additional image and pathology datasets. Specifically, triple negative breast cancers, cysts and low-resolution images acquired from mobile ultrasound devices (eg, GE VScan) are proving to help dramatically improve system efficacy across a wider range of case types expanding our utility and impact. New Area Under the Curve (AUC) analyses significantly outperform any, indeed, all human interpretation of like datasets. Accuracy and/or quality debates will be resolved with performance data. We are confident Koios SmartUltrasound (updated branding for Koios DS) has rapidly become the most accurate source of image ultrasound interpretation available anywhere in the world. (*See Body of Evidence below*)



Workflow Optimization: Two new software releases over the course of 2023 introduced physician requested workflow enhancing functionality.

- Koios Express: Users asked “why must I launch another application?”. We answered, “you shouldn’t” and we delivered. A new 2023 release (ver 3.3) now allows running Koios SmartUltrasound solely in the background, atop and integrated with any PACS viewers. Highly sophisticated image matching technology combined with new desktop client software was conceived, built and delivered. A great R&D breakthrough. Patent pending. A major customer satisfier.
  
- Optical Character Recognition (OCR) and SmartClick for Thyroid: Customers asked us if we could please help them populate their reports – “reading” and inserting all pertinent information written directly onto ultrasound images such as lesion measurements and locations to eliminate the need to manually type or dictate. Once again, Ajit Jairaj, his R&D team, along with our brilliant software and product engineers delivered. Version 3.4 is now released and out in production optimizing ultrasound workflows in more than 20 countries. No typing, no clicks, no words. Physicians simply evaluate Koios AI generated findings, revise or accept and export to their reports. Voila! #UltraSmart. In multiple languages as well!

### **Publications: Our Growing Body of Evidence**

Two macro events shaped 2023 and accelerated the inevitable. The release and mainstream awareness of OpenAI’s ChatGPT and, “closer to home”, the landmark [MASAI study](#) touting the evidence and impact of Mammography + AI in improving cancer detection (20%) while simultaneously reducing the reading workload.

Koios Nation saw a flurry of seven (7) new peer reviewed publications and/or even more abstracts, presentations and posters. All contribute to our growing body of compelling clinical evidence. All signals point to validating system accuracy, absence of bias and overall clinical efficacy. Published studies are often years in the making. We are grateful for the diligent efforts of our growing legion of research collaborators around the world who provide this all-important confirmation of our claims necessary to justify investments in our technology today and going forward and essential for reimbursement.



**Published studies** featuring Koios DS/SmartUltrasound include the following:

[Accuracy of KOIOS Decision Support as a Valuable Second Opinion for Breast Ultrasound Screening](#) (Koo, Margolies)

[Toward AI-supported US Triage of Women with Palpable Breast Lumps in a Low-Resource Setting](#) (Berg, Jairaj)

[A role for breast ultrasound artificial intelligence decision support in the evaluation of small invasive lobular carcinomas](#) (Amir, Coffey)

[Artificial Intelligence Decision Support for Triple-Negative Breast Cancers on Ultrasound](#) (Coffey, Mango)

[Artificial Intelligence in BI-RADS Categorization of Breast Lesions on Ultrasound: Can We Omit Excessive Follow-ups and Biopsies?](#) (Guldogen, Aribal)

[Validating racial and ethnic non-bias of artificial intelligence decision support for diagnostic breast ultrasound evaluation](#) (Koo, Margolies)

[Assessment of an artificial intelligence-based decision support system in the thyroid nodule evaluation in clinical practice](#) (Fernandez-Velazco, Diaz-Soto)

### **Team Koios**

New additions to support account growth included Deployment Specialist (Dan Kritzer) joining us from EHR/EMR vendor EPIC. We also welcomed two new Enablement & Engagement specialists (Jo Barnes & Robin Allman), both former practicing sonographers, to support on-boarding, training and adoption and increased utilization as well as providing valuable input to our Product team. Our new VP of Product (Jon Robinson) joined us late in the year after an 18-year tenure in product management at Intelrad, one of the world's leading Radiology (PACS) solution providers. We are fortunate to have them and they are making their impact felt.

### **Reimbursement & Regulatory Advances**

Over the course of 2023 customer updates indicated increasingly positive responses from private payers related to insurance coverage & payments for the use of our SmartUltrasound technology. The new CPT Category III codes released in early 2022 are now readily available and accessible to practices when combined with a traditional breast or thyroid ultrasound exam.



Payment rates are ranging from \$50/case to a robust \$150+/case (varying by location, payer and patient health plan). Improving prospects for reimbursement incentives helps drive adoption and makes our Koios SmartUltrasound's strong business case even more compelling. The road to AI success must pass through the threshold of delivering a strong, measurable return on investment (ROI). Our "return on artificial intelligence" is among the best in the business.

Regulatory approvals extended our reach into several new markets creating opportunities to commercialize in response to local demand and our growing distributor network. We received a favorable ruling from Anvisa in Brazil agreeing that Koios DS remain a Class II device.

### **Challenges**

Covid-19 repercussions and headwinds remained in full effect throughout much of 2023. Healthcare in particular faced "long Covid" stress and strain with budgets for new initiatives shelved while internal costs skyrocketed in an overall inflationary environment combined with  $\geq$  20% wage inflation for radiologists specifically. Available funding for new AI solutions was often redirected to address labor shortages. We ultimately believe this will prove to be a benefit to us moving forward as a more expensive workforce will necessitate greater efficiency and productivity.

Radiology thought leaders continue to recommend that decisions to adopt AI be predicated upon a lengthy (and often costly) validation period that can extend up to 12 months and beyond. Despite our growing body of evidence, physicians are advised to approach AI with a healthy dose of caution. Any AI solution must be installed and working effectively within IT environments and proven effective on local patient populations before making funding commitments – a valuable but time-consuming exercise that we must replicate across the vast majority of our new accounts (large and small) before getting agreement to proceed under a commercial agreement. We are not alone. This challenge impacts our colleagues at other companies offering complementary AI solutions across other imaging modalities, slowing commercialization traction while adoption growth is increasingly on the rise.

Hospital and imaging center IT departments have seen a surge in demand for implementation and integration of AI into their health systems placing a strain on limited IT resources. We must contend with a learning curve attributed to what is relatively new technology (imaging AI). We face a lack of customer expertise required to understand, effectively deploy, monitor and manage our solution going forward. Major education campaigns have begun as a new chapter for Radiology AI, similar to what has been seen in conjunction with other major technology led transformations in other industries. We are often asked by our IT counterparts at our customers,



“Please be patient with us, this is all so new. You are the AI experts, we are learning as we go”. 2024 will see more focus on human factors, education and change management.

**As we look ahead into 2024**, we remain inspired, energized, steadfastly focused, committed and cautiously optimistic that the AI adoption tide is turning in our favor; and for the benefit of patients and healthcare systems across the globe. The need is immense and growing.

Goal: Standard of Care.

Promising indicators include:

- RSNA quote requests: 31 (vs. 7 in 2022)
- Deals closed in Dec 2023: 10

Pipeline growth:

- Jan 1: \$3M
- Dec 20: \$5M
- Mar 14<sup>th</sup>: \$8.1M
- Multiple new, large quotes: >\$200K/yr
- Several large, government funded Koios studies are underway from the UK to Indonesia.
- Line of sight/Goal: Break-even in 2025 (likely the first in Radiology AI!)

We have assembled an outstanding team, developed an excellent, ever-improving innovative product in a new, developing and massive market. Patient awareness will start to drive adoption.

Our strategy for 2024 is simple and straightforward: Remain focused, stay the course, efficiently. Keep learning, keep adapting. A disruption to a massive industry is underway. We are the front-lines. Listen to our customers. Build and deliver capabilities needed to be successful in a new clinical paradigm. We have numerous compelling advantages stemming from already having integrated into the Radiology IT ecosystem with partnerships from all major OEM vendors, PACS providers and reporting companies. Our focus is solving challenging clinical and workflow problems and delivering measurable results; both business and societal. Incredibly rewarding.

Budgets for AI projects are being presented to hospital leadership, receiving approvals slowly, advancing prospects for growing our installed base at an increasingly rapid rate. We are ready.

Governments and payers are getting in on the act. We have met directly with representatives from health ministries as well as leaders from the largest payer in the US. During the annual



JPMorgan Healthcare conference in early January, the overwhelmingly dominant theme was “AI”, to elevate care, add value and simply to remain competitive. Music to our ears. We have a phenomenal first mover position with a massive and growing technical and IP “moat” combined with proven results at a time when decision-makers are beginning to make AI a real priority, essential to their strategic plans and commitments to the investment community.

We continue engineering efficiencies into our solution for an even more compelling productivity driven business case while minimizing the IT burden on our customers. Planned for an upcoming release is our newest, low technical impact version: “Koios Lite”. Installed quickly, on-scanner and shipped directly on-device from multiple manufacturers (GE, Philips, Canon & Siemens). Expected later in 2024, early 2025. We also have lymph node data (images and pathology) in our lab. Fasten your seatbelts, an exciting ride continues ahead.

### **Funding Update**

Mid 2022 our Board of Directors approved a \$12M equity capital raise. We subsequently signed a term sheet with our wonderful lead investor, Mitsui & Co and in the fall we closed and funded an initial \$8M tranche in early February 2023 with a plan to complete the balance of the raise (\$4M) in subsequent weeks.

As many of you recall, “things changed” (dramatically) in early March 2023 when the demise of Silicon Valley Bank combined with escalating interest rates created an ensuing “correction” in the private financing markets, resulting in what essentially became a venture funding moratorium. Fortunately, we had substantial capital reserves combined with a conservative growth spending plan that has carried us through to today. In response, we also aggressively pursued accelerating commercial terms with all pilot customers, new prospects and even our hardware partners. GEHC agreed to a \$500K advance on anticipated sales. Other initiatives are underway to secure licensing and prepayments from Canon, Philips and Siemens.

Throughout the fall and into Q4/Q1 we have been regularly assessing what has been a dynamic and challenging private funding market, meeting with potential co-investors, evaluating all fund-raising options.

One thing is for certain. Every move we make must and will be what is best for the Company and in the best interest of our shareholders. I am often asked by physicians, distributors and partners, “Will there ever be an opportunity for me to invest in Koios?” To that end, as part of our funding strategy, we are planning to use US SEC Reg CF (Regulation Crowdfunding) to open up





this investment opportunity to “friends, family” across our growing “Koios Community” of physician customers, partners and available to you, all of our existing investors as well – at the same terms as Mitsui’s investment into the Company over a year ago. Yes, “should to shoulder” and on the same terms as one of the most accomplished, reputable investors in the world, and our strategic partner. Very exciting. Please let me know if you are interested in learning more.

At the outset of this lofty endeavor we believed part of the Koios story will always be about “democratizing healthcare”. Extending excellent care and innovative technology to patients from all walks of life, to the farthest reaches of the world. Not just the privileged few. Unconfined to any particular geography. In the coming weeks we will officially announce our [WeFunder](#) campaign, a step toward “democratizing” the private investment process creating an opportunity for anyone to invest. Using Reg CF an SPV (special purpose vehicle) will create a single investor entity on our cap table with the prospect of raising up to \$5M in growth capital sourced from within and across our network of future Koios champions and advocates. Interested strategic professional investors may also participate or indicate their intention to co-invest alongside the SPV. Numerous discussions are underway at present.

Please be on the lookout for more information coming soon. We will announce “quietly” to existing investors and other interested parties before larger public announcements. The reception we receive from this new offering will dictate how aggressively we continue to execute our growth plans, expand our product offering and continue impacting lives across the globe.

Thank you again for your continued interest in our exciting Koios story. Our entire team is grateful for your on-going support. We are inspired to make good on the promise of building a great company for investors, an innovative and effective technology for physicians and delivering life-impacting outcomes for patients and their families. Together we are creating a world in which SmartUltrasound will become the standard of care. It is already happening, every day.

**ONWARD!**

Best regards,

A handwritten signature in blue ink that reads "Chad". The signature is fluid and cursive, with a long horizontal stroke at the end.

R. Chad McClennan  
President & CEO  
Koios Medical, Inc.