

A new, strengthened leadership team accelerated the transformation further. First, was the transition of the corporate brand from one that was product focused to one that is patient centric, “Creating a World where Cancer Can’t Hide,” which was successfully introduced at the annual, global Radiological Society of North America meeting in November 2023.

Second, the Company secured a new and extended partnership with Google Health by signing a 20-year partnership to expand 2D AI solutions to encompass an application of AI as the independent, second reader. In addition, the Company completed an integration with GE Health’s MyBreastAI suite by embedding iCAD solutions within GE mammography machines.

And third, the divestiture of Xoft provides iCAD more cash and focus to apply to the foundational Cancer Detection business segment.

Phase 3: Investing in Growth Initiatives

iCAD is actively focused on revenue growth and market expansion initiatives using a three-phased, overlapping approach. Phase one, expanding existing accounts; phase two, growing channels, both direct and indirect; and phase three entering new markets. The first phase, expanding existing accounts, will take advantage of iCAD’s sizable install base, including reengaging customers who’ve lapsed on annual maintenance service agreements, are behind and upgrading to new versions, including the transition to cloud, winning back lost or deeply lapsed customers and accelerating deployment across large national accounts. Large enterprise customers like Solis, Radiology Partners, SimonMed, Ascension and Cleveland Clinic, who collectively serve about 15% of the US mammography screening market, offer great potential for iCAD as many are in the early stages of rolling out iCAD’s solutions and continue to expand into more sites and markets each month. The focus of this phase is to accelerate deployment across national and regional accounts as well as re-engage 1,000 of iCAD’s 4,000 customers who’ve lapsed on their maintenance agreements or who are operating on older software versions.

The second phase is growing channels, direct and indirect, in both the US and globally through direct sales and establishing new distribution partnerships.

Globally, more than 31,000 mammography systems serve approximately 250 million women in the age range recommended for annual mammograms. Expanding to the 63% of the market that is not using AI, plus additional wins in the segment using AI but not ProFound, results in significant opportunity for new business. iCAD has added sales leadership, sales representatives, and sales operations team members, and plans to add distribution partners to focus on new and expanded business given the large addressable market opportunity.

Phase three is focused on entering new markets with new solutions, most likely in fiscal year 2025. One example is the commercialization of the Heart Health solution, which was previously referred to as Breast Arterial Calcification. In the fourth quarter of 2022, iCAD announced a development and commercial collaboration agreement with Solis. This collaboration is focused on using mammography to define cardiovascular risk, a new application that could identify millions of women at risk for heart disease using data obtained from their mammogram. With heart disease being the number one killer among women in the US, this collaboration not only offers the potential to address a significant unmet need in patient care, but also to penetrate a sizable new market. This product is currently available for investigational use as we complete the FDA approval process.

ProFound Breast Health AI Suite

Backed by science, clinical evidence and proven patient outcomes, iCAD’s ProFound Breast Health Suite of cancer detection, density assessment and risk evaluation solutions, provides an unmatched approach to accurately detecting more cancers earlier, providing certainty and peace of mind to providers and patients. The Company’s mission is to see that these solutions be deployed universally as part of a standard of care for breast health in order to achieve its vision of a world where cancer can't hide.

ProFound Breast Cancer Detection

ProFound Detection exposes cancer’s hiding place. It’s clinically proven to improve breast cancer detection and radiologist performance.

The current version, ProFound Detection V3.0, is built with the latest in deep-learning, 3rd generation artificial intelligence, and delivers unparalleled accuracy and efficiency for 2D and 3D mammography screening with up to 2X enhanced clinical performance compared to other AI platforms as accessed in January of 2023 and compared to FDA 510K submissions K182373 (iCAD), K201019 (Hologic) and K193229 (ScreenPoint).

A key competitive differentiator is the fact that iCAD’s algorithms are trained on over 6 million images including one of the largest 3D image datasets gathered from over 100 sites from around the globe. Competitively, iCAD’s algorithm training data includes the highest amount of sourcing from the US, providing diverse data that is ethnically, racially, and age representative of the US population. The